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Chemist&Druggist
The Newsweekly for Pharmacy

18/25 December 2004

Nicorette Patch Product Information. **Presentation:** Transdermal delivery system available in 3 sizes (30, 20 and 10cm2) releasing 15mg, 10mg and 5mg of nicotine respectively over 16 hours. **Uses:** Nicotine dependence and symptom relief in smoking cessation. **Dosage:** Patients should stop smoking and refrain from using any other nicotine products. The patch should be applied to the skin on the hip, upper arm or chest in the morning and removed at bedtime. Application should be limited to 16 hours per day. Initially one 15mg patch daily for 8 weeks. Dose should be reduced to 10mg for 2 weeks and then 5mg for a further 2 weeks. If abstinence is not achieved at 3 months, further courses may be recommended. Not for use by persons under 18 except under advice from a doctor. **Contraindications:** Nicotine is contraindicated in pregnancy and lactation. Non-smokers, known hypersensitivity to nicotine or any component of the patch. **Precautions:** Erythema may occur. If severe or persistent, discontinue treatment. Peptic ulcer, angina pectoris, recent myocardial infarction, serious cardiac arrhythmias, systemic hypertension, peripheral vascular disease, diabetes mellitus, hyperthyroidism, phaeochromocytoma, recent cerebrovascular accident, chronic generalised dermatological disorders. Dispose of carefully. **Pregnancy and lactation:** If the patient cannot give up smoking without NRT then a risk benefit assessment should be made. Side effects: Application site reactions (e.g. erythema and itching), headache, nausea, dizziness, palpitations, dyspepsia and myalgia. **RRP (ex-VAT):** Cartons containing Nicorette patches in single sachets in the following quantities: Nicorette Patch 15mg (PL00032/0294) – packs of 7 (£9.07). Nicorette Patch 10mg (PL00032/0293) – packs of 7 (£9.07). Nicorette Patch 5mg (PL00032/0292) – packs of 7 (£9.07). **Legal category:** GSL. **PL holder:** Pharmacia Limited, Davy Avenue, Milton Keynes, MK5 8PH, UK. Tel. 01304 616161. **PL number:** 15513/0002. **Date of Preparation:** July 2004. **Reference:** 1. Telephone Omnibus Survey, Smoking Cessation, 1010 adults aged 16+, 7-9 Feb 2003.

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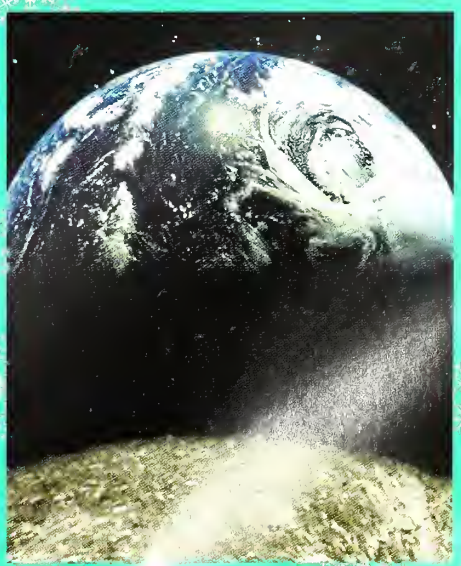
DoH consults on supervision law changes

Scots' global sum up 10.5pc over two years

New Shipman report looks at self-regulation

Brave new world: beyond the contract



New packaging now available.

Sudafed. A clear view of a bigger market.

Sudafed are targeting more sufferers than ever before with a £3 million ad campaign to make sure we reach every one of them. The ads show that when Sudafed unblocks your nose, it puts you back in touch with your senses. With this kind of support the only congestion you'll be suffering from will be in your shop. So stock up now.

Unblock your nose. Unlock your senses.

[illegible] Congestion Relief Capsules Product Information. Presentation: Phenylephrine hydrochloride 12mg. Uses: Relief of nasal congestion associated with colds and hayfever. Dosage: Adults and children [illegible] up to 4 times a day. Not suitable for children under 12 years. Should not be used for longer than 7 days without medical advice. Contraindications: Hypersensitivity to any of the ingredients [illegible] diabetes, closed angle glaucoma, hyperthyroidism, prostatic enlargement, phaeochromocytoma and use of MAOIs in the preceding 14 days. Precautions: Occlusive vascular disease including [illegible] tricyclic antidepressants, other sympathomimetic drugs, vasodilators, beta blockers or enzyme inducers e.g. alcohol. May increase risk of arrhythmias in digitalised patients. Pregnancy & lactation [illegible] Not [illegible] Tachycardia, cardiac arrhythmias, palpitations, hypertension, nausea, vomiting, headache and occasionally urinary retention in males. RRP (ex VAT): 12 £2.49, 24 £4.49 Legal category GSL. P[illegible] Company PLC, Nottingham N[illegible]AA. PL number: 0001 4/0593. Further Information available from Pfizer Consumer Healthcare Walton-on-the-Hill KT20 7NS. Date of preparation: July 200[illegible]

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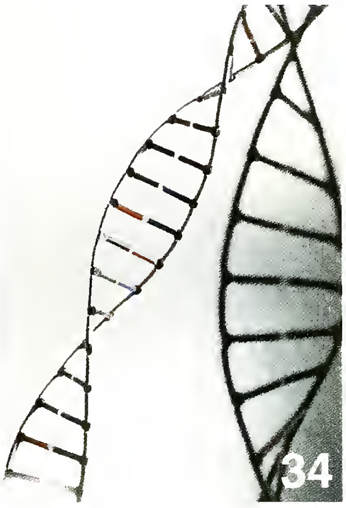
This week

Pharmacy

Regulars



Features

DoH seeks views on supervision changes

by Adrienne de Mont
ademont@cmpinformation.com

The Department of Health is seeking views on proposals to relax the rules on pharmacy control and supervision, allowing pharmacists greater flexibility in patient care. The changes also aim to put pharmacies on an equal footing with other retail outlets on the sale of GSL medicines.

A consultation paper, *Making the best use of the pharmacy workforce*, published this week, suggests changes to primary legislation to allow pharmacists to leave their premises to carry out other professional duties.

"The law will make clear that the responsible pharmacist does not have to be physically present in the pharmacy at all times .... with the support of appropriate technologies and standard operating procedures, transactions requiring pharmacist supervision might be undertaken remotely or the pharmacist might delegate these activities to pharmacy staff that are suitably qualified and accredited to take on these tasks," says the paper.

Maintaining the supervision *status quo* "will do little to address current uncertainties" and may lead to Statutory Committee decisions or court cases testing the boundaries of what is permissible, the document says. Another option would be to amend the law so that supply of POM or P medicines no longer requires the pharmacist's presence in the pharmacy at all times, but Parliament will need convincing that there is enough evidence to support such a change, it adds.

Registered and qualified pharmacy technicians or another suitably accredited member of staff such as a nurse or healthcare assistant could take on a supervisory role.

A pharmacy would be able to supply POM and P medicines where the responsible pharmacist:

- is physically present in the pharmacy
- is present but has delegated supervision and sale to a suitably qualified person (as above) so as to provide services elsewhere on the premises, for example in a consulting room
- is not physically present but can meet supervision responsibilities remotely with the aid of modern technologies and supported by clinical governance and SOPs in the pharmacy
- is not physically present but has delegated supervision and sale to suitable staff, enabling the pharmacist to provide services off the premises, undertake CPD or contribute to developing local health strategies.

Comments are invited on how long a responsible pharmacist may be absent from the premises.

The document also makes a case for addressing the anomaly of 'personal control' on the sale of GSL medicines in pharmacies while there is no such requirement when the same medicine is sold in other outlets.

Patient safety is paramount, the DoH stresses. The pharmacist should retain overall responsibility for ensuring proper procedures are in place for the dispensing and sale of medicines and that staff keep to these procedures. There should be arrangements for checking the appropriateness of the prescription and giving advice to patients or carers at the time of medicine sale or dispensing.

The requirement for corporate bodies to appoint a superintendent pharmacist will continue.

Freeing the pharmacist from supervising dispensing will improve public safety by extending patients' access to clinical advice and help with getting the best from their medicines. The paper points out that it takes five years to train a pharmacist, yet many spend much of their time on routine dispensing. The requirements also limit opportunities to recruit and train others to undertake the technical aspects of dispensing in a more cost effective way.

Views should be sent by March 11, 2005, to Mary Grafton, Department of Health, Room 518, Eileen House, 80–94 Newington Causeway, London SE1 6EF (e-mail: *Mary.Grafton@dh.gsi.gov.uk*). The Welsh Assembly Government and Health Departments in Scotland and Northern Ireland agree in principle with the proposals but there will be separate consultations in these countries.

SPGC agrees £10m rise in global sum

SPGC has unanimously voted for a two-year funding deal for Scottish contractors that will see the global sum rise 6.36 per cent from £93.235 million to £99.171m this year.

This will be followed by a 3.9 per cent rise in 2005–06, leading to a £103.039m global sum. In addition, the £2.399m overspend identified for the previous year will be written off. The new 'transitional' funding arrangements came into effect on December 1 and will last until March 31, 2006. Funding for the new contract, due for roll out in April 2006, is still to be negotiated.

Also for both 2004–05 and 2005–06, any spending for oncost, direct supply pilots and model schemes in excess of the 2003–04 spend of £2.899m, will be met by the Scottish Executive on top of the global sum payment.

SPGC chair Frank Owens said: "Throughout our discussions we have been keen to secure not just the principle of no detriment to the global sum but also, as far as is reasonably possible within a fixed global sum, no detriment to individual fee income.

"This agreement will provide for a period of stability, giving security of income while we continue to work on new contract service specifications and look to develop financial models to inform funding negotiations for the new contract."

As a first step to moving away from a volume based contract, SPGC says the new package is a transitional arrangement where contractor fee income is determined on the basis of last year's fees together with access to global sum uplift monies.

SPGC says that, if it hadn't agreed this, it would have had to address the global sum overspend from 2003–04 and re-balance this year's dispensing fee, which could have resulted in a fee cut of 7p, putting at risk the chance to access new funding above the global sum.

Earlier this year, a £2m infrastructure support fund for the new pharmacy contract was also agreed. Of this, £0.5m will be issued equally to contractors by the end of March 2005 for IT support; £0.75m will support staff training; and at least £0.5m will be for premises improvement.

SPGC, which will publish full details of the funding in its *Vision* newsletter next week, is also in discussion with the SEHD to secure ring-fenced funds to support weekend pharmaceutical services. This funding is likely to be available from next April, and will be in addition to the global sum, SPGC says. Discussions are also taking place on funding community pharmacist prescribers to set up clinics.

SEHD and SPGC have also agreed that the current situation of pharmacists using purchase profits to subsidise pharmacy running costs is unsustainable and that greater transparency is needed in reimbursement and remuneration models. They add that details on new arrangements will be released in due course and these will be revenue neutral.

Season's greetings

We would like to thank all of our readers, contributors, suppliers and advertisers for your continued support throughout 2004 and to wish you all a happy and prosperous 2005.

In lieu of sending out Christmas cards, we are making a donation to two charities, the Leukaemia Research Fund and CLIC – Cancer & Leukaemia in Childhood – which offers practical, hands-on care including financial and emotional support as well as clinical services.

PPRS moves

PPRS price changes will apply to items dispensed in February 2005 onwards and not for January prescriptions, PSNC and SPGC have announced.

In order to protect contractors, pharmacy bodies have negotiated with respective health department to implement the price changes one month later.

The *C&D Price List* will have the updated prices on its *www.dotpharmacy.com* website from Friday December 31, in the supplement on January 8, and in the February *Price List*.

Shipman Inquiry prompts regulatory review

by Fiona Salvage
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The RPSGB will examine its regulatory role in the wake of the Shipman Inquiry's latest report into the regulation of doctors.

The Government published its response to the Inquiry's findings on CD regulation simultaneously with the release of the report.

The Inquiry's fifth report focused on the General Medical Council and its investigative and disciplinary procedures; however, many of the issues are common to other allied self-regulating health professions such as pharmacy.

It will trigger a close look by the RPSGB of its own regulatory systems. Mandie Lavin, RPSGB director of fitness to practise and legal affairs directorate, said the Society would be considering Dame Janet Smith's recommendations regarding complaints procedures, disclosure of information and accountability to see how much it already complies.

Dame Janet's recommendation for professions to have a separate adjudicatory body "is not our current structure or our view of the future," said Ms Lavin. Revalidation every five years and requiring evidence of "fitness to practise" could impact on pharmacy too: Ms Lavin said although the RPSGB will have mandatory CPD from January, it will look at whether to include fitness to practise as well.

The Society will also need to make a detailed analysis of its complaints handling, she added.

Furthermore, Dame Janet's suggestion of laying annual reports before a Commons health select committee would introduce parliamentary accountability to professional organisations such as the RPSGB and the GMC. It would allow statistical analysis of disciplinary procedures to identify trends and practice of statutory committees.

Speaking about the release of the Government's response to the fourth report, health secretary John Reid said the Government fully accepts "the need to improve current arrangements for the management of Controlled Drugs, and to do so in a way which does not hinder patients from accessing the treatment they need" (*see page 10 for the full report*).

Accepting many of the Inquiry's recommendations, the DoH has estimated that the set-up costs will total £5.2 million and the running costs will be £7.8m each year. However, £2.8m of the annual running costs will be shared among GPs and community pharmacies.

For more information
www.the-shipman-inquiry.org.uk

Update knockout

GENUS PHARMACEUTICALS

Pharmacy Update Knockout 2004 goes into its final stages this month with only eight players left in with a chance of scooping the £3,000 prize pot put up by sponsor Genus Pharmaceuticals.

Those who so far have successfully answered all Update modules in 2004 and returned their test papers are: Linda Vernon (Ascot); Sue Sears (Dorking); Margaret March (Weston-Super-Mare); Michelle Warner (Ashington); Tara Arnold (Parkgate, Co Antrim); Hazel Barton (Glasgow); Nicola Entwistle (Strongbourne) and Julie Dubniewytsch (Dimmington). See page 18 to sign up for Update Knockout 2005, again supported by Genus Pharmaceuticals.

RPSGB seeks to nip poor performance in the bud

by Asha Fowells
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The Royal Pharmaceutical Society is releasing guidance on setting up local schemes to manage pharmacists' poor performance.

The document aims to deal with poorly performing pharmacists at an early stage rather than allowing problems to escalate, necessitating disciplinary action, the Society's Council emphasised last week.

Initially in draft form, the RPSGB will invite comments and feedback before publishing a final version for England and Wales.

The main topics covered in *Setting up Local Schemes to Identify and Remedy Pharmacist Poor Performance in England and Wales* are: expected performance levels; recognising sub-standard practice; complaints and the role of the RPSGB; dealing with locums, proprietors and employees; how to develop a local scheme; appraisals and performance reviews; appeals procedure; supporting and assessing improvement; relevant support and resources.

John Murphy, general manager of employee and locum organisation the Pharmacists' Defence Association, said: "It is in everyone's interest that there is a process that is consistent for all stakeholders. As risk managers we welcome any move to rectify poor performance rather than go through disciplinary action. Support for sub-standard pharmacists is the operative word."

But he added: "I'm a bit sceptical as to whether PCOs can provide the support needed to locums in the ways organisations do for their employees, and it'll depend whether resources are available." In addition, he called for performance management schemes to be transparent, describing it as "key in helping pharmacists achieve competence".

e-pharmacy examined

The Royal Pharmaceutical Society has agreed changes to the Code of Ethics requirements for online pharmacy services.

At a meeting last week, Council member Pat Hoare said the Society needed to ensure e-pharmacies operated safely to protect patients. The Council-agreed amendments comprise:

- including the superintendent pharmacist's name (if applicable),
- details of how to confirm the registration status of the pharmacy and pharmacist,
- clear identification of the pharmacist assuming professional responsibility for medicines' provision to each patient,
- complaints procedure details.

The agreed Code of Ethics revisions pre-empt the formation of a group that will consider the issues around the rapid growth and regulation of internet pharmacy. This will include representatives from many organisations, including the MHRA, pharmacy and medical bodies, e-pharmacy providers and lay persons.

NHS logo

Community pharmacy can show its allegiance to the NHS by using new logos unveiled by health minister Rosie Winterton at the Barry Shooter Pharmacy in Essex.

The logo, which shows the pharmacy green cross above the blue NHS insignia, can be found at *www.nhsidentity.nhs.uk/pharmacy* or by calling 08701 555455.

Pharmacist fined for contract fraud

A pharmacist from Walsall was convicted last week of fraud after he falsified land registry papers to secure a pharmacy contract in Dudley.

Mazair Iqbal was fined £6,000 for two charges of forgery and ordered to pay £400 prosecution costs. He now faces disciplinary proceedings before the RPSGB.

Dudley Beacon and Castle PCT awarded Mr Iqbal a contract to run an NHS pharmacy service after he claimed that he owned a property in the area where the pharmacy was commissioned to be run from.

But investigation by the PCT's counter fraud specialist and the NHS Counter Fraud Service revealed that the land registry documents he had presented to the contract panel were forgeries. Mr Iqbal, who already runs three pharmacies in and around Birmingham, pleaded guilty at Dudley Magistrate's Court.

A spokesman for the NHS Counter Fraud and Security Management Service said: "Mazair Iqbal has jeopardised the pharmacy care that the people of Dudley need, and has tried to cheat his way to a contract that was meant to benefit patient care, not line the pockets of a fraudster."

Lloyds puts up £10k

Lloydspharmacy is offering £10,000 to students who complete four years' continuous service.

The loyalty bonus is restricted to pharmacy undergraduates who undergo their pre-registration training with the pharmacy chain. The company described the one-off payment as a "helping hand" with the financial burden of tuition fees and accommodation costs.

HR director Maxine Harris said: "We want them to be able to concentrate on developing their professional career as a pharmacist and of course ease the transition from being a student into their working lives. This payment will recognise the effort and commitment they give to Lloydspharmacy."

Numark hits 1,700

Sunil Patel of Ronchetti's Chemist, Enfield, has become Numark's 1,700th member. Proprietor of four pharmacies, Mr Patel says he was attracted by the virtual chain's reputation and professionalism, and because he gained the advantages of being part of a group but retained his independence. He added: "Their assistance with preparing for the new contract is really helping me get on track."

Obituary

Bronnley has issued the following statement following the death of a former director, Tom Stocker.

"It is with regret we announce that Tom Stocker, a much loved and well respected industry figure, has died in his 84th year last week. He came to Bronnley as a salesman in 1955 and remained with the company until 2000. He rose from being a salesman to a director with the company he loved so much.

"Many of you will remember him as a charming and effective man and a keen sportsman. Our thoughts are with his family."

UniChem MD

David Coles is managing director of UniChem, not chief executive as our picture caption said last week (*C&D, December 11, p4*).

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Taunton pharmacies treat infections on NHS

by Adrienne de Mont
ademont@cmpinformation.com

Nearly all (17 out of 18) pharmacies in Taunton Deane Primary Care Trust have been accredited to supply POM or P medicines for certain minor conditions.

The specially trained pharmacists can provide – under a patient group direction – miconazole for athlete's foot, clotrimazole for candidiasis and ringworm, chloramphenicol ointment and eye drops for conjunctivitis, trimethoprim for cystitis and Bactroban for impetigo. The patients pay a prescription charge if they are not exempt from NHS charges.

The choice of medicines was based on those requested in a 12-month pilot in one pharmacy. The latest scheme is permanent and might be extended to include other medicines.

The pharmacists receive around £5 for professional advice on each supply plus the cost of the medicines. The scheme is advertised throughout the PCT, including GP surgeries, and patients self-refer.

Shaun Green, the PCT's director of training and medicines management, said: "We want to see modern, quality-driven pharmacy services in Taunton and expand the role of the pharmacist throughout the district. We hope that this kind of development will allow pharmacists to help patients, while reducing their need to see a GP or contact out-of-hours medical services."

Society reviews fees

The Royal Pharmaceutical Society is reconsidering its position on the registration fee for non-practising pharmacists.

At a meeting last week, RPSGB president Nicholas Wood asked Council to revisit its decision to introduce a three-year phased increase in the non-practising fee to the level of one third of the practising fee. Saying members' concerns needed allaying without undermining Council's decisions or impacting negatively on the Society's financial position, Mr Wood asked for three options to be considered:

- Pegging the non-practising fee at £46, with increases only at the rate of inflation.
- Phasing in an increase in the non-practising fee only to cover the *Pharmaceutical Journal* subscription and the cost of processing the member's details (about £60).
- Offering a reduced cost or free subscription to the *PJ* to long-serving members who choose to leave the Register.

Linda Stone said the cost implications of all options needed assessing before Council could make its decision, and suggested referring the matter to the RPSGB resource management committee. The item could then be considered by Council next year, she said.

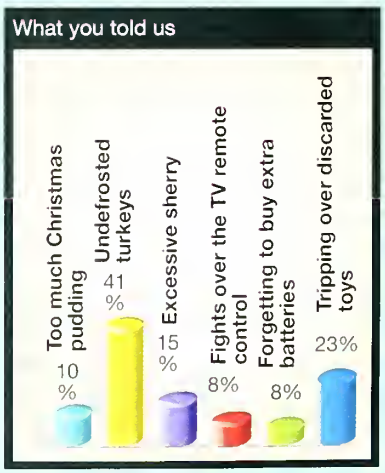
Questiontime

Last week we asked: What do you think will be the biggest threat to public health this Christmas? You replied (see right):

This week's question: Which of the following will you resolve to give up in the New Year?

- Overspending
- Smoking
- Membership of the RPSGB
- Your white coat
- The final check

You can record your vote on our website: *www.dotpharmacy.com* You have until noon on January 4 to cast your vote. We will publish the results in *C&D*, January 8.



Met Office pilots early warning role

The Met Office has started a pilot aiming to prevent hospital admissions from COPD, which is exacerbated by cold weather and the higher incidence of respiratory infections in winter.

It has devised a computer model that predicts when sufferers in eight SHAs are likely to be at increased risk, based on weather and virus level data. The early warning system will enable PCTs to make sure those at-risk people are looked after, with measures such as checking they have their heating on and are eating properly. In more severe cases, an outreach nurse might visit a week before the patient is at maximum risk.

The project will run until April and is funded by the PCTs and SHAs involved. The Met Office says this is the first pilot of its type in the world.

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NiQuitin CQ 21, 14, 7mg Transdermal Patches, NiQuitin CQ Clear 21, 14, 7mg (nicotine) opaque or transparent transdermal patches 21 mg, 14 mg, 7 mg nicotine (Steps 1, 2, 3) for relief of nicotine withdrawal symptoms during smoking cessation. Dosage: stop smoking completely. *>10 cigarettes/day;* Step 1 for 6 weeks, then Step 2 for 2 weeks, then Step 3 for 2 weeks. *<10 cigarettes/day,* Step 2 for 6 weeks then Step 3 for 2 weeks. Complete full course. Max 10 consecutive weeks. Apply to fresh site (clean, dry skin) once daily. **Contraindications:** non/occasional smokers, children under 12. Recent MI/ stroke, severe arrhythmia, unstable/worsening/ resting angina. Hypersensitivity. **Precautions:** adolescents 12-17 years, cardiovascular disease including uncontrolled hypertension; severe renal /hepatic impairment, peptic ulcer, hyperthyroidism, insulin-dependent diabetes, phaeochromocytoma, dermatitis. Concomitant medication may need dose adjustment. **Side effects:** Local rash, itching, burning, tingling, numbness, swelling, pain, urticaria, heaviness. Depression, irritability, anxiety, nervousness, restlessness, mood lability, drowsiness, impaired concentration, insomnia, sleep disturbance. Allergic reactions, abnormal dreams, nausea, vomiting, dry mouth, GI disturbance, headache, dizziness, palpitations, tachycardia, tremor, dyspnoea, pharyngitis, cough, arthralgia, myalgia, sweating, chest pain, fatigue, malaise, flu-like symptoms. **Pregnancy/lactation:** try without nicotine replacement therapy. Medical assessment of risk/benefit if necessary. **GSL. PL** 00079/0347, 0346, 0345, 0350, 0355 & 0354. **PL holder** GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS U.K. **Pack size** and **RSP:** All strengths 7 patches £17.49, Stop 1 only 14 patches £22.95. **Date of revision:** March 2004

NiQuitin CQ, CQ and Click2Quit are trade marks of the GlaxoSmithKline group of companies.

Pharmacy's future after Shipman

The Government has responded to recommendations in the fourth Shipman report. Fiona Salvage picks out the key messages for pharmacists

As the fifth report of the Shipman Inquiry was laid before Parliament last week, the Government published its response to the fourth report focusing on Controlled Drugs.

Both reports will affect dramatically the way pharmacy operates in the high street and the Society's regulatory role, but, on the whole, the mood from the professional bodies is positive to Inquiry chairman Dame Janet Smith's recommendations.

The Government has agreed with a large proportion of Dame Janet's proposals, but has rejected some for being too cumbersome or time-consuming with no obvious gain for patients or practitioners.

Proposals include tightening up monitoring and inspection procedures, increasing the availability of information on prescribing privileges or clinical conditions for the appropriate people, creating audit trails and running balances for CD registers. It will mean extra work for pharmacists, but much of it can be seen as current good practice and when electronic prescribing is introduced the burden should lessen.

Besides electronic prescribing, electronic CD registers and monitoring of prescription data will all play their part in easing the administrative processes.

Prescribing

For now, GPs will continue to issue handwritten CD prescriptions because the Government has disagreed with Dame Janet's proposal for special CD prescription pads and copying out information by hand on computer printed prescriptions until ETP is in place. A unique 12-digit code on prescription forms will be used to identify prescribers, their practice and PCT in future systems; however, the number's omission should not invalidate the prescription. A CD prescription's validity will be limited to 28 days, with the possibility of exceptionally extending this by endorsement. In addition, a CD prescription should contain not more than 28 days' worth of the drug except in exceptional circumstances.

Key recommendations

- Running balances for CD registers.
- Requiring ID from person collecting CD prescription.
- Pharmacists able to amend technical errors on CD prescriptions.
- Pilot of Patient Drug Record Card scheme.

Dispensing

Asking individuals and healthcare professionals for ID when collecting CDs and entering this information into the CD register will become legislation after the Government amends the *Misuse of Drugs Regulations 2001*. Where there is no ID – and guidance will clarify what ID is acceptable – the dispenser can use their discretion to supply the CD and will not be committing an offence. For healthcare professionals without ID, pharmacists will have discretion to dispense after seeking corroborative evidence.

The Government will amend legislation to allow pharmacists to dispense against CD prescriptions with technical errors and where the prescriber's intent is clear. It will also explore allowing pharmacists to dispense against prescriptions with technical errors where the clinical intent is not fully clear but a safe judgement can be made against the "underlying therapeutic intention".

CD registers

When electronic CD registers come into general use, a mandatory requirement for running balances will also come into force. Periodically, pharmacists will need to transmit data to a central repository for reconciliation. Pharmacists will need to keep secure electronic CD registers for up to 11 years.

The Government will pilot a scheme of patient drug record cards (PDRCs) for patients receiving injectable Schedule 2 CDs. The PDRCs will show prescribing, dispensing and administering details and when completed will be returned to the central data repository, rather than PCTs as Dame Janet suggested.

Destruction and disposal

Patients' unused CDs should be returned to the pharmacy to be destroyed. The Government will amend legislation to make clear that healthcare professionals may remove unwanted CDs.

Pharmacists destroying CDs will need an independent witness who is also lawfully entitled to destroy CDs (eg a pharmacist from a different company). The Government recommends that the list of authorised persons should be "sufficiently broadly drawn so as not to interfere with the delivery of patient care at pharmacies and dispensaries".

Guidance and inspecting

The National Prescribing Centre will publish updated guidance on CDs by the end of March. This will be updated as legislation is passed, said Clive Jackson, NPC chief executive. It will also be developing a training programme for those involved in pharmacy inspections, such as chemist inspection officers, RPSGB inspectors etc, to help them understand and effectively analyse prescribing data.

This will be important as the Government has not totally agreed with Dame Janet's proposal for a multidisciplinary inspectorate. Instead, it proposes a named officer in each PCT with responsibility for the monitoring and inspections carried out by RPSGB and Healthcare Commission inspectors, CIOs and PCT staff, who will be obliged to collaborate with each other.

Future prescribers

The important thing is that the recommendations do not suggest removing CD prescribing privileges from nurse prescribers now or from future independent prescribers, says Mr Jackson. It gives patients "access to a range of professionals, which is good", he concluded.

Implementation timeline excerpts

January to August 2005

- New inspection arrangements.
- Promoting electronic generation of prescriptions and electronic CD registers.
- Reach agreement with RPSGB on including CD aspects into routine community pharmacy inspections.
- Amend legislation for e-prescriptions and e-CD registers.

September 2005 to March 2006

- Regulate normal validity of CD prescriptions.
- Regulations allowing pharmacists to amend technical errors on CD prescriptions.
- Evaluated pilot study of PDRCs.
- Begin patient information campaign on safe storage of medicines and return to pharmacies.

April 2006 to March 2007

- Legislate to require pharmacists to prepare PDRCs for each issue of Schedule 2 injectable drugs.
- Set up systems to capture and analyse prescription and PDRC data.
- Issue good practice guidance on PDRCs.

April 2007 onwards

- Consider feasibility for setting up secure internet site listing prescribers with restricted prescribing.
- Requirements for pharmacies to send information from e-CD registers for collation and analysis.
- Mandatory enhancements to pharmacy CD registers including running balances.

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Comment from the Editor

Our question to pharmacists this week was: What do you think will be the biggest threat to public health this Christmas?

"Undefrosted turkeys – but fighting over the remote control applies in my house!"

Shabbir Damani, King's Lynn

"Too much sherry"

Elizabeth Griffin, Kingston-upon-Thames

"Too much sherry. I'm a teetotaller but I presume that causes the most problems"

Masrat Nisar, Kings Heath

As the year draws to a close, and the nation goes into a siege mentality, stocking up for the one day that the shops will be closed, news tends to be a bit thin. Not this year.

Three big stories have brought the pharmacy year to quite a significant end. The implications of the much-heralded consultation on pharmacy supervision, the Shipman Inquiry's last two reports, and, for Scotland, an interesting remuneration deal should give pharmacists much to think about over the festive period.

Taking them in turn, the Government's proposals for freeing the pharmacist from the bind of the dispensary and medicines counter, and even the pharmacy, will no doubt raise a chorus of concern from pharmacists young and old. It is 15 years since the profession voted against giving up the 'final check' of dispensed prescriptions. But even today, a straw poll of pharmacy undergraduates suggests that some new entrants to the profession believe the only way a pharmacist can be truly in control is to have the final say on when the medicine is given out.

Having good procedures in place will allow pharmacists to delegate more and more routine work

But pharmacists should not necessarily fear this proposed new freedom. As we enter an age of ever-increasing accountability, with audit and standard operating procedures a part of professional ethics and the new contract, pharmacists will begin to understand that having good procedures in place will allow them to delegate more and more routine work.

Look at the sale of OTC medicines – the sales protocols which the RPSGB introduced in the 1990s have caused few problems for patients but mean the pharmacist does not have to be involved in every sale. And now, with the new contract about to start, pharmacists will need to be out of the dispensary if they are to secure a better income as well as address recruitment and retention. The new money will be for those enhanced services where money is not ring-fenced for pharmacy but open to any practitioner. However, if pharmacists do not take the opportunities these proposals present, they may find other professions encroaching on these long-requested new roles.

Bear in mind though that there must still be a balance. One of the successes of the current community pharmacy service is that the public now expects to be able to obtain professional pharmaceutical advice without an appointment; but if the pharmacist cannot be consulted on demand, that goodwill could easily be lost.

Goodwill is something that the GMC would like. The last Shipman Inquiry report was damning of the doctors' regulatory body, and the national media extrapolated this to ask whether any professional group could be expected to regulate itself. Pharmacy has had a much better system in place and is perhaps unfairly tarnished by these generalisations. But even though the profession has gone through a painful period in revising its professional code and Charter, the actions of the medics could cause further unhappiness.

In Scotland, the good news is that a two-year transitional payment period will lead away from volume-based payments towards a hybrid system that will include capitation payments, implying patient registration. This will be a great opportunity to build on the already excellent patient-pharmacist relationship, improving professional standing.

After another turbulent year, then, is pharmacy heading into smoother waters?

TOPICAL REFLECTIONS

Oh for a forward-looking PCT by the sea

I wish my PCT would carry out a pharmaceutical needs assessment. Or maybe it has, but not taken it any further. The assessment carried out by Brighton and Hove PCT (*see C&D, Dec 11, p40*) has got local pharmacists working on a number of schemes that benefit everyone.

This assessment seems to have triggered interest in contractors where previously there was none. I empathise with the quoted pharmacist: "I have been here since 1988 and this is the first time I have had anyone from the NHS take an interest in what I am doing." I often feel that the local NHS is not particularly interested in me other than to ensure that I cover rotas and collect returned medicines. Brighton pharmacists are the lucky ones because medicines compliance, minor ailment schemes, smoking cessation services, patient group directions could be provided by all pharmacists if their PCTs were keen.

Pharmaceutical services may end up being provided on a postcode basis, varying widely depending on the PCT. Relaxed control of entry regulations could mean more pharmacies opening in areas with greater funding available for services. Contractors may even want to 'swap' their business to another area depending whether they want to concentrate on services or prefer a dispensing factory.

But I'm not looking to open a business in Brighton yet – I'll keep plugging away with the LPC and hope my PCT sees the light eventually.

Personal control wrangle leaves me cold

The debate about personal control continues to rumble on, leaving me none the wiser about how or why anything has changed. According to David Reissner (*C&D, December 11, p20*), a statement of intent from the DoH to abolish personal control and an erroneous 'clarification' from the Society have ruffled a few feathers and now nobody wants to resolve the issue.

It sounds like so much legal and technical wrangling to me. Meanwhile I have a business to run and must remain pragmatic. In answer to Mr Reissner's rhetorical question, "is clarification needed?", I would suggest not.

Everyone knows that personal control must be relaxed, if not abolished, and it is simply a question of when. The more forward thinking among us will have this at the back of our minds when considering business plans. I didn't know that a pharmacist had to be on the premises of a pharmacy for GSL medicines to be sold until recently, but this requirement has apparently been around since 1937 anyway. It is crazy that petrol stations can sell GSL medicines without any advice whatsoever but whether the DoH will consider it worthwhile to sort this issue in isolation I'm not sure.

I suspect that the Department will relax the personal control legislation simultaneously with a clarification of exactly what personal control is. But then I'm not a lawyer.

In the meantime I will exercise personal control as I always have, visiting the toilet and the bank when necessary. And I look forward to a relaxation of the rules in due course as an inevitable step towards my professional development.

And another question...

The Society's annual retention fee form seems to get bigger and more financially demanding every year, but these forms are never as bad as they look once you get round to sitting down with a pen and the right frame of mind.

I thought this form could be a useful way to get more feedback from the membership about topical issues. Responses to surveys are always poor, as shown by the response to the Charter vote, but a couple of extra questions of the retention fee form may elicit a better response because they would require little additional effort. Assuming the Society wants more feedback from its members, that is.

BlackBAG

When the fog clears

Something very strange was going on as I walked into the Kilkenny Bar, Ireland. Drinkers lined up against the huge plank of elbow polished timber as you would expect of any Irish pub.

Pints of dark beer guaranteed to cure anaemia sat in rows. Glasses hung from the underside of the roof like translucent haemorrhoids. But I felt a sort of acrophobia. Realisation soon came: "Of course, I can actually see the far side of the room." More to the point, I could breath without the use of an oxygen enricher.

A pleasant part of my job involves giving evening talks to Irish pharmacists. As Ireland is officially the best place in the world to live it must *de facto* be the ideal place to give lectures. This only applies if you can get hold of a second-hand liver as Irish chemists err on the side of better hospitality.

Kilkenny is a fair sized town with roughly the same number of souls as Freemantle gaol where most of their ancestors lived courtesy of Her Majesty's Government. Following my

Glasses hung from the underside of the roof like translucent haemorrhoids

presentation 'Pharma Sutra; a pharmacological look at what makes the world go round', I'd accompanied Ned Kelly's children out to the pubs. No smoke. It was like being in Victorian London and being able to see Jack the Ripper. Which brings me to John Reid. What a missed opportunity. What a misplaced belief in so-called freedom. Following the publication of the health White Paper, the 'war against terror' provoked the most restrictive measures ever imposed by a British government. It would be salutatory to compare the number of UK deaths from terrorism to the slaughter from tobacco. Something very strange is going on.

Dr Ian Banks is a GP practising in Northern Ireland

Time to prepare now for enhanced services

Steve Dunn, group managing director of AAH Pharmaceuticals, says community pharmacists should aim high for greater profits

I wonder how much of the enthusiasm with which the great majority of community pharmacists greeted the new contractual framework was due to a sense of relief?

The emphasis still lies largely on dispensing volume, and rather than being enshrined within the contract, as are the essential and advanced tiers, the enhanced level has been written out of it.

Instead of being a national requirement, the most expansive and potentially profitable range of services of all, embracing as it does full clinical reviews, minor ailments and diagnostic services such as cholesterol screening and anti-coagulant monitoring, is down to local negotiation between contractors and PCTs.

After all the uncertainty they have been going through during the contract's long gestation, I'd be the last to blame pharmacists for being thankful that, initially at least, things have not moved as far as was envisaged from the status quo.

But they would be unwise to sit back. It will take time – my guess is up to five years – but the accent on service delivery will steadily and irrevocably become more pronounced.

The DoH has crossed the Rubicon. The march towards more service-led payment has begun and there is no going back. Though the current focus might be on advanced services such as medicines use review (MUR) and prescription intervention, enhanced provision is definitely a-coming.

That should be a source of agreeable contemplation, because enhanced services will not only open up important new revenue streams but will inevitably do what the current contract manifestly fails to do – place community pharmacists right at the heart of the nation's healthcare.

In working with our retail customers to maximise potential where the cash is, we are turning even more focus on how we can best help them set out their enhanced services stall.

That means more than such areas as IT, service delivery, equipment, products, skills sets, training and premises. Into the equation at this level we bring discussing with them how to be fully proactive, how to show the way instead of having the way shown to them.

If pharmacists are successfully to acquire funding from their PCT they will have to demonstrate local need. In other words, it is they who will have to take the initiative. They will have to go knocking on their PCT's door, because I think it highly unlikely that PCTs will go knocking on theirs.

As commissioners, monitors and funding managers of all local NHS services, PCTs are meant to take the lead in developing new pharmacy services, and in supporting the implementation of the new contract by pharmacy contractors.

But how many, I wonder, will do so, or at least do so with fullest will and energy? PSNC says PCTs that have ignored or been sceptical about pharmacy services must change their approach and seek to support and work with their LPCs and local pharmacies, and I share its implied reservations.

All the more so because PCTs faced with finding extra resources for monitoring will argue that the degree to which they can fund enhanced services will be governed by the amount of finance they have available.

Well, there is one solution – get rid of some of them. There are currently 303 PCTs, all with their own expensive middle and top-level management structures. Merging them so that they look more like the Health Maintenance Organisations that work so well in the USA would free up cash that would be best spent on healthcare rather than bureaucracy.

One positive aspect of monitoring, involving as it does PCTs checking how the money pharmacists get from the Government is being spent, is that it will in itself serve to bring the parties closer together.

We are examining with our independent customers how to build on that, how to develop effective relationships and lines of communication with PCTs and to work in partnership with them in delivering local healthcare provision.

It is well worth the effort. There are valuable new streams of income to be tapped into, greater heights to which to aspire. And now, and not some time in the future, is the time for pharmacists to make a move.

"The DoH has crossed the Rubicon. The march towards more service-led payment has begun and there is no going back"

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To POM or to P

Fiona Salvage tries her hand at divining POM launches for 2005

Pollsters would have us believe that the next General Election result can be predicted by opinion polls and popularity stakes.

Predicting which medicines may be launched into the UK market is more scientific than that, but not by much. *C&D*'s predictions for 2004 weren't far off the mark, though (*C&D, January 24, p19*): we correctly predicted the launch of 13 out of the 18 drugs mentioned in the feature. Four are still to be launched, with the remainder temporarily sidelined.

There are many reasons why manufacturers' ambitions to launch their next potential blockbuster might be thwarted. Regulatory agencies take longer than could be thought humanly possible to approve medications (cf Sativex); companies decide to wait until all European approvals are in before launching, then decide to postpone when a similar drug is withdrawn from the market (Novartis, lumiracoxib); and companies get the approval and then don't have enough product in stock (you know who you are).

Despite all these hurdles to bringing a product to launch, it seems that some drug companies are more like Kelly Holmes than Paula Radcliffe and make it to the finishing line.

There is another glimmer of hope, though. Companies can always expand their revenue streams by proposing a medicine to be switched from POM to P status. Chloramphenicol, the switch candidate at the top of every pharmacist's wish list since, well, forever, is looking promising for next year. But it's unlikely to be the only one and we've compiled our list of likely suspects. For now, though, let's concentrate on the POMs.

Central nervous system

Some drugs that were expected to launch last year are still awaiting MHRA approval. Lundbeck's monoamine oxidase B inhibitor rasagiline is a case in point. The company claims it improves motor function in Parkinson's disease patients.

Lilly received a licence for duloxetine this year for stress urinary incontinence indication. It is seeking a licence for the serotonin and noradrenaline reuptake inhibitor to treat depression under the brand name Cymbalta. It was launched in the USA this year.

Sanofi-Aventis says Epilim Chronosphere (sodium valproate) as slow-release microspheres in convenient stick packs should be available next year in a wide range of dosages.

GW Pharmaceuticals is still waiting to hear from the MHRA on its long-awaited cannabis medicine, Sativex. It submitted the application to the agency in March 2003 seeking an indication for improving spasticity in multiple sclerosis.

Observers have been on tenterhooks for months for the product launch, but GW is still waiting for an approving nod. The CSM wants the company to carry out another trial to measure how much benefit patients experience when using Sativex before it considers recommending approval. The company can appeal the CSM's decision, but the earliest a hearing could be scheduled would be in six months' time. If Sativex is launched next year it will be in the second half at the earliest.

Musculoskeletal

Novartis has withdrawn its application for marketing approval for its Cox-2 inhibitor, Prexige (lumiracoxib), for the foreseeable future. Despite receiving approval from the MHRA last year, Novartis has withdrawn from seeking the remaining outstanding European approvals until after the EMEA has conducted its review into the cardiovascular risks of the coxibs, following rofecoxib's recall in September. The company had intended to wait until all European approvals were received before launching the drug.

GlaxoSmithKline and Roche are waiting to hear from the MHRA on their joint project, osteoporosis drug Bonviva (ibandronate). They have submitted applications for once-daily and once-monthly oral dosage indications.

Sanofi-Aventis and Procter & Gamble expect to launch Actonel Combi, a new form of risedronate, their osteoporosis drug.

Cardiovascular

AstraZeneca has launched Exanta (ximelagatran) in Argentina, Austria, Denmark, Finland, Germany, Iceland, Norway, Portugal and Sweden for venous thromboembolic event prevention in major orthopaedic surgery. Exanta successfully completed the EU mutual recognition procedure in May this year, but is not currently licensed in the UK. However, the US Food and Drug Administration issued a non-approvable letter earlier this year citing liver side effects as outweighing the benefits.

Pfizer is awaiting EU approval for its combination treatment for heart disease, Caduet. Already launched in the USA, Caduet contains

amlodipine and atorvastatin and is intended for individuals with high blood pressure or angina and high cholesterol. In addition, Pfizer has put sildenafil – this time under the brand name Revatio – forward to the European regulatory authorities for a pulmonary arterial hypertension indication. It has orphan status in the European review so is likely to go through the approval procedure faster than most.

Oncology

AstraZeneca is still waiting to launch its first-in-class oncology drug, Iressa. Iressa (gefitinib) received approval from the US Food and Drug Administration last year. It is the first in a new class of epidermal growth factor receeptor tyrosine kinase (EGFR-TK) inhibitors. Iressa is currently under review with the European Committee for Proprietary Medicinal Products as a second or third line treatment for non-small cell lung cancer in patients who cannot receive standard therapy.

Avastin (bevacizumab) from Roche is, the company claims, the first treatment that inhibits angiogenesis and will be put to the European Commission for final marketing approval. The European Committee for Medicinal Products for Human Use gave a positive recommendation for Avastin's use as a first line treatment in patients with metastatic carcinoma of the colon or rectum in conjunction with 5-fluorouracil or irinotecan.

Sanofi-Aventis is seeking licence extensions for Taxotere (docetaxel) in conjunction with other oncology products. It is expecting approval for Taxotere with: prednisone or prednisolone for hormone refractory metastatic prostatic cancer; doxorubicin and cyclophosphamide as an adjuvant treatment for operable node-positive breast cancer; and Herceptin (trastuzumab) for metastatic breast cancer (Roche already holds the licence for Herceptin with Taxotere).

Ophthalmology

Macugen is a vascular endothelial growth factor inhibitor for which Pfizer is seeking a licence for treating age related macular degeneration. Data from the company shows the compound reduces the blood leakage which damages the retina.

Endocrine

Angeliq film-coated tablets from Novartis were approved by the MHRA earlier this year. The HRT contains drospirenone and estradiol.

Exubera (inhaled insulin) is a joint venture between Pfizer and Sanofi-Aventis. It was submitted for regulatory approval in February 2004 and the companies say there is, as yet, no date for launch.

OptiClik is a new insulin pen that Sanofi-Aventis expects to launch next year, as it is approved in Europe.

Apidra (insulin glulisine), another Sanofi-Aventis diabetes product, is a rapid acting insulin analogue also due to hit the market in 2005.

Respiratory

Daxas (roflumilast) is a phosphodiesterase-IV inhibitor for which Pfizer is seeking a licence to treat asthma and COPD.

Ariflo (cilomilast) is an oral selective phosphodiesterase-IV inhibitor, this time from GSK. It was submitted to the EMEA in January 2003 and the FDA issued an approvable letter in October.

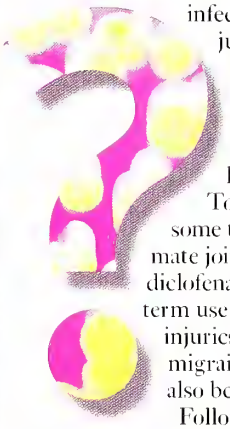
POM to P...lease make this available OTC

All these potential POMs are fine and dandy, but "what new medicines might be available for me to sell and show off my shiny new consultation room?" you may ask.

So, will next year's copies of the *C&D Guide to OTC Medicines & Diagnostics* be bursting at the seams with new OTC products? Maybe. In fact, quite probably. The MHRA is ultra-keen for companies to apply for POM to P switches and so is the Government as part of improving access to medicines.

Chloramphenicol is under consultation already, but what else could be joining it?

If chloramphenicol gets the go-ahead, it is likely to open the door for other antibiotics to go OTC. Not so much the 'thin end of the wedge' and the end of the world the GPs so love to warn us about, but more 'about time too'. How do trimethoprim for cystitis, fusidic acid for impetigo and topical antibiotics for acne sound? Some antifungals are also likely candidates; we predict nystatin suspension for paediatric oral thrush and topical preparations for nail fungal infections could switch to P status. However, judging by some existing POM prices for the latter, these could be prohibitively expensive unless a licence extension for an existing brand of topical antifungals was the conduit.



The analgesia section of the *Guide* may have to go up a few pages next year too. Topical diclofenac has been available OTC for some time now and it's about time its oral stable mate joined it on the shelves. Oral preparations of diclofenac are likely to be granted P status for short term use only for indications such as migraine, sports injuries and dysmenorrhoea. In addition, specific migraine preparations, namely the triptans, could also be looking for a move to OTC.

Following on from this year's switch for omeprazole, classmate lansoprazole could be looking to follow in the former's footsteps.

Now that simvastatin has gone OTC, albeit to a mixed reception, other long-term condition medications could follow suit. There's more than a slim chance that hypertension and asthma medications could go OTC later in the year – perhaps when the furore has died down. Those new consultation rooms appearing in pharmacies up and down the country would be the perfect places to do blood pressure checks and measure peak flows.

For some time pharmacists (and most likely women) have wished for the combined oral contraceptive pill to become medicines. Not forgetting something for the men (or the weekend), erectile dysfunction drugs could be seen on pharmacy shelves in the future. So there you go: lots of good candidates to boost your profits.

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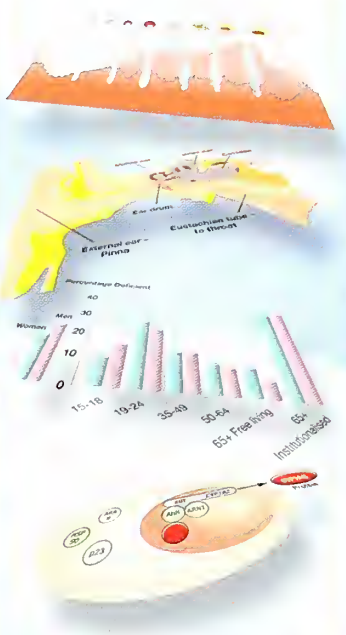

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Hopes that this festive decoration might be a cancer treatment have not been fulfilled, says *Professor Edzard Ernst*

Under the mistletoe

Mistletoe (*Viscum album*) is a parasitic plant that grows on several trees. It has fascinated mankind for millennia and played a part in ancient rituals – of the Celts, for example – as well as in herbal medicine. It has traditionally been used for hypertension, epilepsy, insomnia and depression.

Rudolf Steiner (1861–1925), the founder of anthroposophical medicine, concluded from the plant's parasitic nature that it should be an anticancer remedy: just as the plant lives off trees, cancer lives off the human body. An extract of mistletoe might therefore be a cure for, or at least a symptomatic treatment of, cancer. Steiner's followers popularised mistletoe extracts in the German-speaking world and it gradually became a widespread adjunctive cancer treatment.

Pharmacology

Mistletoe extracts contain lectins, phoratoxins, viscotoxins, amines, choline, histamine, flavonoids, terpenoids and tannins. Depending on the nature of the host tree, the composition can vary considerably.

In vitro experiments confirm mistletoe to have cytotoxic and immune stimulating activities. In addition, mistletoe might be hypotensive, cardiac depressant, anti-inflammatory and sedative.[1]

Toxicology

Commercial mistletoe extracts are usually for subcutaneous injection. They can cause pain and irritation at the injection site, chills, fever, headache, angina, hypotension, eosinophilia and allergic reactions. Taken orally, mistletoe is highly toxic and can cause seizures, coma and death.[1]

Does it work?

The only well-investigated indication of mistletoe is cancer. It is promoted as a cure or symptom relief for most forms of cancer. The most up-to-date systematic review included 10 randomised controlled trials (RCTs).[2] Their methodological quality was varied and often poor. The results were far from uniform. While some of the low-quality studies suggested efficacy in terms of reduction of symptoms, the high quality studies failed to do so. No study showed a benefit in terms of survival or reduction of tumour burden. The authors concluded that "rigorous trials of mistletoe extracts fail to demonstrate efficacy of this therapy".[2]

Despite various claims for medicinal properties, mistletoe's benefits for cancer patients do not outweigh the potential harm

Is it safe?

A long list of serious adverse effects has been associated with mistletoe: bradycardia; dehydration; delirium; diarrhoea; gastroenteritis; hallucinations; hepatitis; fever; seizures; and vomiting.[3] Several fatalities are on record. A recent study even suggested that, in some cancers, mistletoe might stimulate malignant cell growth.[4]

Interactions are conceivable with antihypertensives, cardiac depressants and central nervous system depressants.[3]

How to supply

Because of the variation in commercial products, no common regimen can be suggested and the manufacturer's instructions must be adhered to.

Conclusion

Even though the data are not entirely uniform, the most reliable RCTs fail to indicate that mistletoe injections convey a benefit to cancer patients either in terms of survival, tumour burden or symptomatic relief. Several severe adverse effects have been associated with mistletoe therapy. Thus the documented benefits do not outweigh the potential harm and this treatment cannot be recommended for cancer patients.

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Professor Ernst, MD, PhD, FRCP, FRCPEd, is professor of complementary medicine, Peninsula Medical School, Universities of Exeter and Plymouth.

No game of conkers

There is good evidence that horse chestnut seed extract helps chronic venous insufficiency, according to *Professor Edzard Ernst*

Adyenne Hart-Davis Science Photo Library

Everyone knows the horse chestnut tree, *Aesculus hippocastanum* (genus *Aesculus*). It was introduced into northern Europe in 1576 by the botanist, Charles de L'Ecluse, who brought seeds from Constantinople. The name allegedly comes from the fact that horse chestnut seeds were fed to horses when they suffered from respiratory problems.

The seeds are also the part of the plant that is used for human medicines. These chestnuts or conkers are poisonous but the toxic ingredients are removed from the extract that is used medicinally. Traditionally, seeds were recommended for oral use to treat varicose veins, haemorrhoids, respiratory diseases, diarrhoea and malaria. Today the seed extracts are used mainly for venous problems. Both topical and oral applications are available.

Pharmacology

Horse chestnut seed extracts (HCSE) contain triterpene saponins, flavonoids, tannins, quinones, sterols and fatty acids. The extract has been shown to possess anti-exudative, anti-inflammatory and immunomodulatory activity. The principal component active for treating venous conditions is the saponin escin. This compound has been shown to inhibit the activity of elastase and hyalurinase enzymes, which are involved in the breakdown of proteoglycans in the skin's underlying support structures. These enzymes may also play a part in leukocyte activation, as studies have shown increased levels of leukocytes in affected limbs.

Other evidence points to an increased serum activity of proteoglycan hydrolases in patients with chronic venous insufficiency (CVI), which can be reduced with HCSE.

Does it work?

A systematic review included 13 double-blind randomised controlled trials of oral HCSE for the treatment of CVI (*Table 1*).[1] Eight of these studies were placebo-controlled. Their results suggest that HCSE is effective in reducing subjective symptoms (such as feeling of heaviness) and objective signs (for example, oedema) of CVI. Five comparative trials implied that HCSE is as effective as reference treatments such as hydroxyethylrutosides.

More recently, a further

Continued on page 22 ▶

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Table 1: Double-blind randomised controlled trials (RCTs) of horse chestnut seed extract (HCSE) for chronic venous insufficiency

Author (year)	Methodological quality	Study design	Number of patients	Medication (Dosage)	Treatment period	Main end point
Rudolfsky et al (1986)	High	Two parallel groups	40	HCSE (1 capsule twice a day) *	4 weeks	Leg volume
Bisler et al (1986)	High	Crossover	24	HCSE (1 capsule twice a day) *	Not applicable	Capillary filtration coefficient
Pilz (1990)	High	Two parallel groups	30	HCSE (1 capsule twice a day) *	20 days	Leg circumference at ankle
Diehm et al (1992)	High	Two parallel groups	40	HCSE (1 capsule twice a day) **	6 weeks	Leg volume
Friederich et al (1978)	High	Crossover	118	HCSE (1 capsule twice a day)	20 days	CVI-related symptoms
Lohr et al (1986)	Moderate	Two parallel groups	80	HCSE (1 capsule twice a day)	8 weeks	Leg volume
Neiss and Böhm (1976)	Moderate	Crossover	233	HCSE (1 capsule twice a day) *	20 days	CVI-related symptoms
Steiner (1990)	Moderate	Crossover	20	HCSE (1 capsule twice a day) *	2 weeks	Leg volume
Kalbfleisch and Pfalzgraf (1989)	High	Two parallel groups	33	HCSE (1 capsule once a day) HR (500 mg/day) *	8 weeks	Leg circumference at ankle and calf
Rehn et al (1996)	High	Three-armed parallel groups	155	HCSE (1 capsule twice a day) HR (1000 mg/day [loading dose for 4 weeks, then 500 mg/day [for 8 weeks]) *	12 weeks	Leg volume
Diehm et al (1996)	Moderate	Three-armed parallel groups	240	HCSE (1 capsule twice a day *); (compression therapy/placebo)	12 weeks	Logarithmically transformed leg volume
Erdlen (1989)	Moderate	Two parallel groups	30	HCSE (1 capsule twice a day) * ß	4 weeks	Minimal ankle circumference
Erler (1991)	Moderate	Two parallel groups	40	HCSE (1 capsule twice a day) * HR (2,000 mg/day)	8 weeks	Leg circumference before and after oedema provocation

All studies suggested efficacy of HCSE. HR = 0-(beta-hydroyethyl)-rutoside.
* = standardised to 50mg escin *ß = standardised to 75mg escin

independent systematic review confirmed these results.[2] One trial (n = 240) suggested similar effects of HCSE and compression therapy.[3] For its topical use there is little evidence from rigorous clinical trials.

Safety

Because no positive safety data are available, HCSE should not be taken during pregnancy and lactation. Pruritus, nausea, gastrointestinal tract symptoms, headache and dizziness were reported as adverse drug reactions (ADRs) to HCSE.

In many studies, the frequency of ADRs with HCSE use was not significantly different from that with placebo. In an observational study involving more than 5,000 patients with CVI, ADRs occurred in 0.6 per cent of patients during treatment with HCSE.[4]

Gastrointestinal tract symptoms and calf spasm were reported most frequently. Adverse drug reactions are also reported from other symptomatic treatments for CVI.

Theoretically, HCSE could increase the effects of anticoagulants and antidiabetic drugs. It could also displace protein-bound drugs.[5]

Dosage

For internal use 250–310mg extract twice daily, corresponding to a daily dose of 100mg aescin. For external use, apply cream three times per day.

Conclusions

There is good evidence that HCSE alleviates the symptoms and signs of CVI. It is, however, not a causal therapy (only vascular surgery is). HCSE is relatively safe but herb-drug interactions should be considered.

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Professor Ernst, MD, PhD, FRCP, FRCPEd, is professor of complementary medicine, Peninsula Medical School, Universities of Exeter and Plymouth.

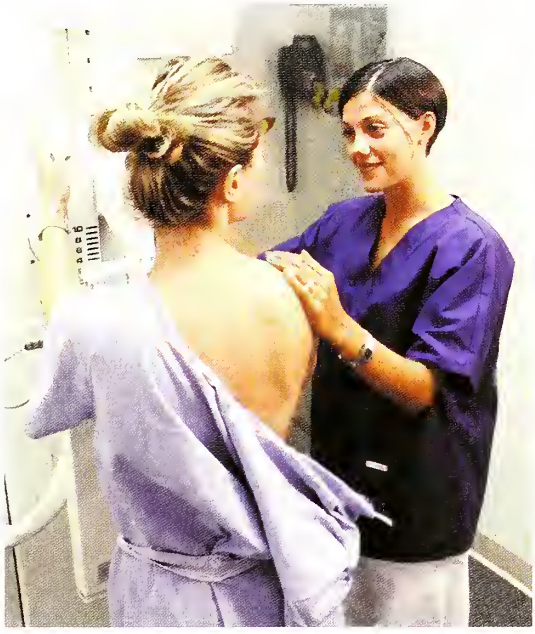
Folic acid may be linked to breast cancer

Research claiming that taking folate supplements throughout pregnancy could increase a mother's long-term risk of breast cancer should be treated with caution, charities have warned.

The research team, from Aberdeen and Bristol Universities, followed up a 1960s study in which 2,928 pregnant women were randomly assigned various daily doses of folate supplements: either 0.2mg, 5mg or a placebo. By the end of September 2002, 210 women had died, with 31 deaths attributable to breast cancer, 40 to cardiovascular disease and 112 to cancer. However, the authors did stress this could be a chance finding and urged further studies in this area.

In women who had taken high doses of supplementary folic acid, the risk of dying from breast cancer was twice as great as those taking no folate, and the overall death rate was about 20 per cent higher.

Association for Spina Bifida and Hydrocephalus executive director Andrew Russell, said: "ASBAH's advice is that all women considering pregnancy should take folic acid at 400mcg a day, whilst women with a history or close relatives with spina bifida or anencephaly should take the prescription dose of 5mg a day.



Charities have expressed caution over claims that folate supplements in pregnancy increase breast cancer risk

This research does not have statistical significance, and is not of sufficient scientific merit for any women contemplating pregnancy to omit taking a folic acid supplement."

Antonia Bunnin, director of policy and campaigns at Breakthrough Breast Cancer, said: "These are preliminary findings which should be treated with caution – folate has known health benefits and other studies have suggested it may help prevent breast cancer in some women.

More research is needed into the long-term effects of folate intake on breast cancer risk before firm conclusions can be made."

The report's author, Dr Andy Ness, said: "It is entirely possible that this is a chance finding – so further scientific studies are required to examine the association, if there is one, before we reach any conclusions.

"It is important that we don't confuse women about the need to take folic acid supplements early in pregnancy."

Exelon shows effect on PD dementia

Rivastigmine (Exelon) has been shown to moderately improve dementia symptoms in Parkinson's disease sufferers, but with higher rates of some side effects, researchers have announced.

The study found that sufferers who received rivastigmine (3mg-12mg daily for 24 weeks) experienced some improvement in a wide range of symptoms, including memory, concentration and behavioural problems. Rivastigmine patients had a mean improvement of 2.1 points on the Alzheimer's Disease Assessment Scale from a 23.8 baseline; placebo patients had 0.7 points worsening from a 24.3 baseline. In patients treated with rivastigmine, the most common side effects were nausea (29 per cent, compared to 11 per cent of placebo patients), vomiting (17 per cent, compared to 2 per cent) and tremor (10 per cent, compared to 4 per cent).

The study lasted for 24 weeks and 410 patients completed the study. Patients who received rivastigmine started on 1.5mg and doses were increased by 3mg per day in four-week intervals to a maximum of 12mg and the highest well tolerated dose was sustained until the end of the study.

Lead UK investigator Dr Jane Byrne said: "Rivastigmine has demonstrated an improvement across a wide range of dementia symptoms and importantly does not appear to aggravate Parkinsonian symptoms and is relatively well tolerated. Any improvement in Parkinson's disease dementia, especially in behavioural symptoms, offer hope for up to 40 per cent of people with PD who go on to develop dementia."

Welcoming the study, Linda Kelly, chief executive of the Parkinson's Disease Society, said: "We know that for people with Parkinson's and their carers how difficult it is for them to manage the symptoms of dementia. This study shows that better treatments are on the horizon which will help improve the quality of life for people living with this distressing condition."

For more information:

New England Journal of Medicine 2004; 351: 2509-18

Scriptlines

Hexopal transfer

Sanofi-Aventis has announced it has transferred the rights to produce and market Hexopal (inositol nicotinate) tablets to Clonmel Healthcare's subsidiary Genus Pharmaceuticals.

Hexopal enquiries should be made to Genus Customer Services on 01635 568400. Calls for medical information should continue to be made to Sanofi-Aventis until the marketing authorisation transfer is complete, expected next March.

For more information:

Genus Pharmaceuticals
Tel: 01635 568400

Zamadol Melt

Viatris Pharmaceuticals has added a 60-tablet pack of Zamadol Melt (tramadol) 50mg to its portfolio.

Price: £7.66

Pack size: 60 tablets
Viatris
Tel: 01223 205999

Dalivit stocks

LPC Medical has announced that stock of 50ml Dalivit drops is available from major wholesalers including AAH, UniChem, Mawdsley, Brooks and Phoenix.

However, stocks of 25ml Dalivit multivitamin drops remain limited, says LPC.

LPC Medical now holds the licences for other former Eastern Pharmaceutical Licences products, which are: Ispagel Sachets; Hills Balsam cough range; Uvistat sun range; Cepton skin range; Hemocane cream; Nupercainal cream; Easistix pregnancy and ovulation kits; Ranzac 75; Richmond anaesthetic cream; Librofem; Doan's backache pills; Angitak spray; and Psorin ointment.

For more information:

LPC (Pharmaceuticals) Ltd
Tel: 01582 560393
www.lpcpharma.com

Dr Falk transfers

Provalis will transfer the Dr Falk range of products to be marketed by Dr Falk Pharma UK from January 1. Salofalk (mesalazine), Budenofalk (budesonide) and Ursofalk (ursodeoxycholic acid) will be distributed by UniDrug Distribution Group.

For more information:

Dr Falk Pharma UK
Tel: 01628 536600
UniDrug Distribution Group
Tel: 01773 510123

UniChem adds appeal to own-brand range

UniChem is relaunching its own-brand products with new packaging designed to provide an eye-catching, consistent look to the range.

The UniChem range aims to provide pharmacies with own-label products which offer quality alternatives to leading brand products at a more competitive price.

UniChem claims its products are formulated to be of equal quality to the leading brands, featuring the same active ingredients and format. The range has a 'trusted by pharmacists' positioning.

The new look is being introduced this month with the launch of Junior Ibuprofen Suspension and Fluconazole. Bronchial cough Mixture is being relaunched this month with a new look.

The company plans to launch 17 new own-brand products during 2005 subject to MHRA approval. Key categories include allergy, cough and cold, baby, digestive, pain relief, surgical and women's health.

New products will be supported by point of sale material and consumer advertising. A pharmacy information centre will be launched in 2005 to include a 24-hour information line for consumers.

For more information:
UniChem Ltd
Tel: 020 8391 2323

Gentle touch for intimate female care

Linderma is launching a feminine wash especially for women who suffer from mild intimate irritation.

Dercomme Femme Feminine Wash has been developed to provide comfort by re-establishing the natural pH of delicate tissues.

The pleasantly perfumed product is formulated to gently cleanse the external area of the vagina and to help protect against minor irritations.

Intimate irritation can occur following exercise, sex, deodorant use and frequent washing. It can also occur during puberty, during menstruation and the menopause. These factors can disturb the natural pH balance of a woman's sensitive intimate areas, leading to itching, soreness, dryness and an unpleasant odour.

Price: £4.99
Pack size: 200ml
Pip code: 310-8891
Linderma Ltd
Tel: 01981 250124

Lozenges come in new flavours

Zeon Healthcare is relaunching its Zinc Advance range of maximum strength zinc lozenges with more appealing taste and eye-catching new packaging.

The lozenges are now individually wrapped and come in two new variants – Juicy Blackcurrant and Smooth Honey.

The taste has been improved for the existing flavours – Refreshing Eucalyptus and Fresh Lemon. They contain 15mg of zinc (100 per cent of the recommended daily allowance).

Price: £2.99
Pack size: 18
Countercall Ltd
Tel: 01484 536344

Dr Johnson's wipes up

MPM Consumer Products is adding two natural wipes to its Dr Johnson's Mosquito & Insect Repellent range.

Dr Johnson's Mosquito & Insect Repellent Wipes are DEET-free and contain only natural plant extracts including citronella, eucalyptus, lemon grass and lavender.

The pleasantly fragranced wipes can be used by the whole family for protection against mosquitoes and other flying insects. They contain witch hazel and aloe vera.

Price: £1.99
Pack size: 10 wipes
MPM Consumer Products
Tel: 0161 231 6111

Benylin posters deal with a bad spell of coughing

Benylin is launching a poster campaign to reinforce its position in the winter ailments market.

The outdoor campaign uses the slogans "Coff, coff off" and "Benylin – to turn your cough off." Posters will appear on escalator panels, billboards, the sides of buses and in cinemas across the UK. Pfizer Consumer Healthcare claims this will make Benylin the largest outdoor pharmaceutical advertiser.

The new posters form part of the £3 million television and poster campaign with Benylin Chesty Coughs Non-Drowsy and Benylin 4 Flu as its 'hero' products. It aims to grow market share for the core range while increasing awareness and recommendation of Benylin 4 Flu.

Television advertising will continue with the 'Waiting room' commercial running until January.

A press campaign this month has been encouraging people to treat coughs from the outset.

Joanne Heathcote, senior product manager, commented: "We're particularly excited about this campaign, as this will bring Benylin to the forefront of the category, reaching a younger audience. The message of 'Nothing is more effective without prescription' will still be communicated with both the poster and TV adverts, reminding consumers of Benylin's efficacy."

For more information:
Pfizer Consumer Healthcare
Tel: 01304 616161

Alberto adds more style

Alberto-Culver will launch a new hair styling line into its Alberto VO5 range in January.

The VO5 Air Style range contains a new complex called Stylair, formulated to give hair long-lasting hold but reduce stickiness and stiffness. The range comprises five unisex styling products:

Crackling Wax Spray is a light crackling wax spray to add texture and shine without greasiness. Smoothing Souffle is a light cream to tame unwanted frizz and flyaway hair, giving firm hold. Whipped Mousse is a textured mousse to give firm hold, body and bounce to longer hair.

Spritz Gel is a fast drying transparent gel in a fine spray to give hold and control to short layered styles and shoulder length hair. Melting Gelee is a clear, non-sticky product to give lift and body.

Price: All products £3.99

Alberto-Culver Co UK Ltd
Tel: 01256 705000

Promotion

Brand focus

Head lice – the facts

Anyone can catch head lice. The belief that head lice are associated with poor hygiene is totally unfounded. They have no preference to hair type, colour, length or style. Head lice are only contracted through direct head to head contact and cannot jump, swim or fly. This is why infestation is most common in school-age children.

Prompt action is vital when treating head lice. Studies show that the most effective way is to use an insecticide treatment such as **Lyclear Crème Rinse**.

Lyclear Crème Rinse

Lyclear Crème Rinse is a clinically proven 10-minute treatment for head lice infections that is quick and easy to use.

The active ingredient, Permethrin, is based on pyrethrins – insecticides originally derived from chrysanthemum flowers.

Unlike many other treatments, **Lyclear** is suitable for asthmatics and is therefore suitable for children from the age of 6 months.

Lyclear Crème Rinse should be applied to clean, wet hair similar to a conditioner and rinsed out after 10 minutes.

Lyclear is the head lice treatment most recommended by pharmacists and pharmacy assistants (*TNS data, June 04*).

For further information on the management and treatment of head lice v... www.headliceadvice.net

Frontshop

Oxy hits the spot for Mentholatum

The Mentholatum Company has purchased the Oxy brand of teenage acne skincare products from GlaxoSmithKline Consumer Healthcare.

Orders, distribution and invoicing for Oxy will be handled by GSK until the end of February 2005. From March 1, this will be taken over by Boehringer Ingelheim and Pharma Consumer Care who handle the rest of the Mentholatum brands in the UK.

A spokesman for Mentholatum said: "With two licensed medicines in the Oxy range, it has a much stronger healing proposition than many of the 'cosmetic' products on the market and we look forward to developing the brand even further."

Mentholatum plans to support the Oxy range with a mix of cinema, radio and strategic TV advertising plus website activity and in-store promotion in 2005.

For more information:
Mentholatum Co Ltd
Tel: 01355 848484

TV

Bassett's Soft & Chewy Vitamins: GMTV, Sat

Beechams All in One: All areas except U, CTV, GMTV

Beechams Max Strength throat lozenge: All areas except U, CTV, GMTV

Benylin All areas

Bisodol: Sat

Breathe Right nasal strips: GMTV

Calpol: All areas except U

Covonia: B, G, Y, HTV, CAR, TT, five, GMTV, Sat

Hall's Soothers: U, STV, C, HTV, W, LWT, C4, five, GMTV, Sat

Imodium: All areas

Lemsip Max Cold & Flu Lemon: All areas except CTV

Lemsip Cold & Flu Sinus 12hr: All areas except CTV

Lemsip Max Sinus All-Night Decongestant spray: All areas except CTV

Meltus: five, GMTV, Sat

Nicorette: All areas except U, GMTV

NiQuitin: All areas except U, GMTV

Nytol: All areas except U, GMTV

Olbas for Children: five, GMTV

Olbas range: five, GMTV, Sat

Palmer's Cocoa Butter Formula: C4, Sat

Seabond: All areas

Setlers: five, GMTV

Strepsils: All areas except U, GMTV

Sudafed: All areas except U, GMTV

Zovirax: C4, five, Sat

PharmaSite for next week: Cough Nurse night time liquid – window, **Cough Nurse night time liquid –** in-store, **Pepto-Bismol –** dispensary

Anglia, B-Border, C-Central, C4-Channel 4, Five-Channel 5, Carlton, CTV-Channel Islands, G-Granada, GMTV-Breakfast Television, GTV-Grampian, HTV-Wales & West, LWT-London Weekend, M-Meridian, Sat-Satellite, STV-Scotland (central), TT-Tyne Tees, U-Ulster, W-Westcountry, Y-Yorkshire

P&G withdraws Vicks Baby Balsam

Procter & Gamble has begun a voluntary withdrawal of Vicks Baby Balsam from retailers across Europe.

The move follows P&G's agreement with the French Regulatory Agency (AFSSAPS) to withdraw Baby Balsam from pharmacies in France.

The French action is in anticipation of the completion of a study by AFSSAPS to develop new recommendations for France on the levels of essential oils in health and cosmetic products.

This follows two recently reported health effects in children in France who were using Baby Balsam along with prescription medication. No casual link has been established between the effects reported and Baby Balsam.

P&G says it is confident that Baby Balsam is safe when used as directed. However, it has decided on a voluntary European withdrawal because a withdrawal in France will confuse retailers and consumers elsewhere in Europe and undermine consumer trust in the product. This is not a recall from consumers and P&G will carry the full costs for the withdrawal. Pharmacies should return the product to their wholesaler.

For more information:
Procter & Gamble UK
Tel: 0800 169 4085

Holiday closures

- Aventis will close its distribution centre from midday on December 24 and reopen on January 4. Customer services will close on December 27 and 28 and again on January 3. Out-of-hours on-call service for emergencies only will be available as normal during the holiday.
- Boehringer Ingelheim will close from 2pm on Dec 24 and reopen on January 4. Customer services will open from 10am until 3pm on December 29, 30 and 31. Emergency cover for orders and urgent medical information enquiries will be available at other times (01344 424600).
- Distriphar distribution centre will close from midday on December 24 and reopen on January 4. Customer services will close on December 27, 28 and January 3. Out-of-hours on-call service for emergencies only will be available as normal during the holiday.
- Novartis Pharmaceuticals will close its main switchboard from 5.30pm on December 24 until January 4. Medical information will be available until noon on December 24 and from 10am until 4pm on December 29, 30 and 31. Customer care (for orders) will be available until noon on December 24 and from 10am until 3pm on December 29, 30 and 31. An emergency medical information service will be available outside these hours on 01276 698370.
- Pfizer will be closed on December 23 and reopen on January 4. Last deliveries before the holiday will be made on December 23. Normal deliveries will resume from January 4.

Shark attack for Calpol kid

Pfizer Consumer Healthcare is backing Calpol with a £724,000 TV advertising campaign on air nationally until December 31.

A docu-drama style commercial centres on the imagination of three-year-old Louise Harman.

Louise is at home on a footstool, surrounded by sharks in her make-believe ocean. Her play is disturbed when she gets a fever and her mum comes to the rescue with Calprofen.

The commercial closes with a pack shot showing bottles of Calprofen and Calpol and the strapline "If you've got kids you'll understand." The commercial is the first in a series of three Calpol docu-drama style advertisements focusing on kids being kids.

Calpol recently won the award for Best Health Product for 2004 at the *Mother & Baby* magazine awards.

For more information:
Pfizer Consumer Healthcare
Tel: 01304 616161

Scholl Flight Socks campaign lifts off again

SSL International is supporting Scholl Flight Socks with a £500,00 TV campaign in the New Year.

Targeting skiers and winter holidaymakers, the campaign will appear on GMTV throughout January.

The commercial warns that one in 26 flyers can develop a blood clot that could be a potentially fatal deep vein thrombosis (DVT). Compression hosiery and exercise are recommended as effective methods of reducing the risk.

For more information:
SSL International Plc
Tel: 0161 654 3000

Tiger Balm roars into action in the press

Tiger Balm topical analgesic is appearing in a press advertising campaign in lifestyle, health and fitness magazines until January.

The campaign features the circular gold top of the Tiger Balm jar with the image of an athlete soothing the gel into his leg.

The advertising uses the headline 'use tiger power for your everyday aches and pains'.

Ruth Gresty, Tiger Balm's UK brand manager, says: "The campaign is designed to communicate the power, efficacy and strength of the product."

For more information:
SSL International Plc
Tel: 0161 654 3000

New Year boost for Kool 'n' Soothe for children

Kool 'n' Soothe for Kids will be back on TV in a £500,000 campaign in the first quarter of 2005.

The advertising is designed to remind parents that Kool 'n' Soothe Kids is a non-drug solution to the discomfort of high temperatures and fevers in children.

The campaign also highlights Kool 'n' Soothe Migraine – the adult version that offers immediate cooling relief for migraine and severe headaches.

According to manufacturer Kobayashi, 60 per cent of purchasers of Kool 'n' Soothe Kids recognise the product from TV advertising while nearly 50 per cent recognise Kool 'n' Soothe Migraine from TV.

For more information:
Maverick Sales & Marketing Ltd
Tel: 01628 478555

Bathtime with E45

Crookes Healthcare is extending its E45 range of hypoallergenic skincare products with foaming bath milk for children.

E45 Junior Foaming Bath Milk is a two-layered formulation with gentle cleansers and moisturisers designed to appeal to a child's imagination.

The product is shaken before use to combine the soft, creamy foam with soothing milk.

It is suitable for caring for dry skin on children of all ages from 12 months and has been approved by dermatologists and paediatricians.

The formulation is free from perfume, colour and soap.

Price: £4.49
Pack size: 500ml
Pip code: 303-4113
Crookes Healthcare Ltd
Tel: 0115 953 9922

THANK YOU
Diabetes UK

UniChem would like to wish all our customers seasonal greetings and a prosperous New Year.

Instead of sending Christmas cards, UniChem has donated £[illegible] on behalf of all our pharmacists to our nominated charity, Diabetes UK (registered charity no. 215199). www.diabetes.org.uk

UniChem

I'm a pharmacist –

True to form, 2004 was full of the usual ups ands downs as Government reforms and professional disputes again hit the headlines. Gary Paragpuri takes a look at some of the memorable events

After a bumpy 2003, pharmacy was no doubt looking forward to a calmer 2004. There was the promise of a new Charter from the Royal Pharmaceutical Society; three new community pharmacy contracts; and a continuing realisation from the various health departments that pharmacists can offer the NHS and patients so much more.

But, much like last year, 2004 is drawing to a contentious end. The legal spat between the Save Our Society campaign and the RPSGB has landed four pharmacists with a £300,000 bill; the various devolved administrations continue to roll out their pharmacy reforms; and PSNC faced a vociferous minority opposed to the proposed funding for the new contract – a pity considering the contract itself was universally welcomed as one of the most

Pharmacists in the news

Pharmacists get into the news for a wide range of reasons. Here's a selection of stories from 2004 that featured people from the profession

January 10

Brian Conn

The New Year started with a bang for this Essex pharmacist who tracked down a burglar by using his patient medication records. One of the many pharmacists who had to deal with violence this year.

May 1

RPSGB library

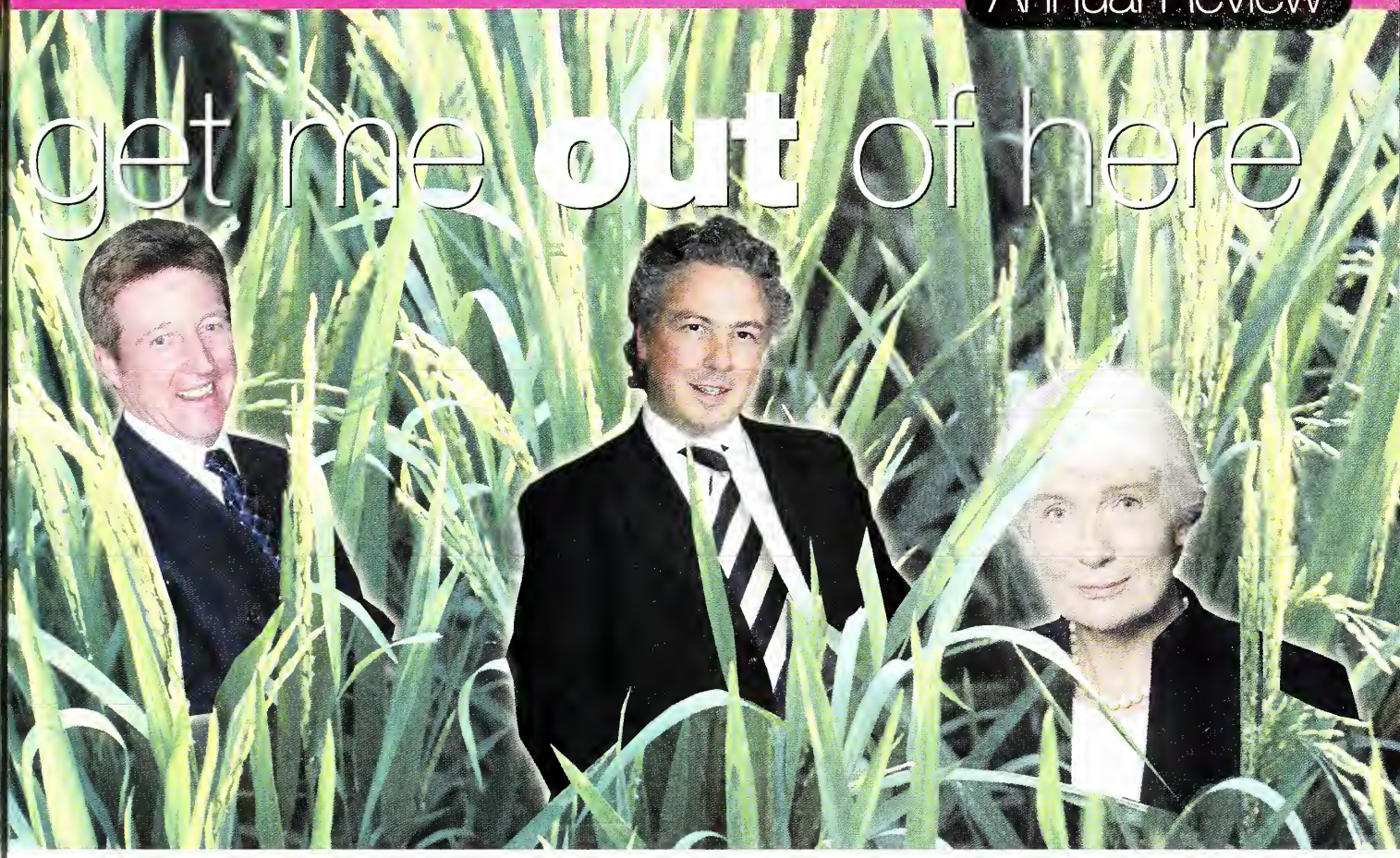
The RPSGB library had a starring role in unearthing the secrets behind King George III's madness. Librarian Roddy Morrison helped the experts determine that arsenic could be contaminating antimony used in 'James's Fever Powder', which was administered to the King.

May 8

Marathon runners

Year in year out, pharmacists put themselves through physical and mental torture to raise money for charity. Pharmacists Carol Watson and Sarfraz Hussain joined teams from Coty UK and Thornton Ross and marathon supremo GP Howard Stoate MP to undergo the torture known as the London Marathon.

get me **out** of here



significant advance ever in recognising community pharmacists' skills.

The first big community pharmacy story to dominate the news was the rise in violence against pharmacists and their staff. *C&D* ran a campaign to alert stakeholders to the issue and reported on an Essex pharmacist who was knocked unconscious during a robbery; Jersey pharmacists who were instructed to beef up security after a spate of break-ins; London contractors who were subject to knife attacks; and a Scottish pharmacy that was twice targeted by armed robbers. Following the campaign, pharmacists gained access to NHS conflict resolution training, and health minister Rosie Winterton announced that violence against pharmacists was unacceptable and would not be tolerated.

Over at Lambeth, the debate over the RPSGB's Charter continued to rumble on after the 2003 special general meeting. The Society submitted a Charter petition to the Privy Council late last year and, while the counter petition by 11 past RPSGB presidents may not have come as too much of a surprise, the High Court challenge by the SOS group did seem to catch the Society on the hop.

The SOS argued that Council members had exceeded their authority in petitioning for the Charter. The RPSGB stood firm and, come the May showdown, the judge ruled in the Society's favour and concluded that the Council was lawfully able to seek a new Charter without getting members' consent.

But if the Society thought the ruling would end the public fighting, the results of the election for Council changed everything. All seven SOS candidates were elected, adding to the three already on Council. To members' surprise, a new Charter was agreed, one that gave greater prominence to the Society's representative role. Even a referendum was promised.

All looked rosy as pharmacists voted in favour of the new Charter. But, once again, the RPSGB came under fire, as the Charter was amended before submission to the Privy Council. The Charter finally came into force earlier this month but, as yet, most pharmacists have yet to see the final version.

So at last the RPSGB has its Charter. But the public arguments over the past two years have not done much to promote the profession

Continued on page 30 ▶

July 10

Fundraisers of the year are Mukesh Shah and Dilip Maroo who organised a 10km sponsored walk for 135 people that raised £17,760 for NSS Polio Hospital India, Macmillan Cancer Relief and the National Asthma Campaign. Costs were covered by Sigma Pharmaceuticals.

The Oshwal pharmacists

July

Carwen Wynne-Howells

Was a member of the soroptimist team on *University Challenge – The professionals* earlier this year. However, the team only scored 55 points so didn't get through to the finals, but we think it's impressive to make it there anyway.

Graham Edmunds

October 23

Pharmacy's gold medallist. Graham won his Paralympic gold medal for swimming as part of the 4x100m GB relay team. Then he met the Queen at Buckingham Palace.

Let's just hope that we don't look back in a few years and wonder where so many smaller contractors have gone

in either the public's or the DoH's eyes. We can only hope for a more united 2005.

The second half of the year saw the various UK community pharmacy contracts take centre stage. England and Wales, having already agreed the framework, then voted in favour of the proposed funding, and an April 1 start date was set. Scotland is not far behind, having set out its contract framework, while Northern Ireland is balloting contractors this month on its framework.

In general, pharmacists have welcomed the new frameworks, as they ensure the profession will finally get paid for the clinical services it has long wished for. But Scotland and Northern Ireland will no doubt have noted the unseemly row that followed PSNC's proposed funding distribution for England and Wales.

Some contractors dispensing fewer than 2,000 items per month bemoaned the lack of fair funding for all, while PSNC argued that it had incorporated several safeguards in the proposal. Either way, the arguments were academic, as contractors voted in favour of the contract. Let's just hope that we don't look back in a few years and wonder where so many smaller contractors have gone. It is after all the very diversity of the community pharmacy network that drives innovation for patients' benefit.

But the new contracts, far from assuring community pharmacy's future, may well compound an existing problem: the need for a large, secure, capable workforce. There is a desperate shortage of pharmacists in parts of the UK and it is not uncommon for shops to

October 30

David Meyer

David Meyer obviously wanted to have a good go at being a millionaire, and he came pretty close to it too.

November 13

Linda Stone was recognised by the Queen for her services to the NHS in the West Midlands. We say: congratulations and good hat.

Linda Stone OBE

Next Year

This could be you! If you're feeling missed out because we didn't mention your exploits this year, well maybe you didn't tell us. Send in your exploits with pictorial evidence to the *C&D* office or e-mail us at *chemdrug@cmpinformation.com* and put 'Back Issues' as the subject

have a different locum each day. If this recruitment and retention malaise is not addressed, then it may be only a matter of time before technicians are put forward as the solution to pharmacy's workforce problem (note the consultation on supervision launched this week).

In October, Dr Karen Hassell told the RPSGB that a third of the Register was inactive and a third of the remainder worked part-time. She added that the attrition rate among pharmacy undergraduates was much higher than perceived and that women pharmacists, who formed the majority of the Register, were also leaving it more quickly and working fewer hours. A Pharmacists' Defence Association survey fuelled the debate this month by suggesting that mandatory CPD coupled with increased retention fees would deter part-time pharmacists from practising. A fifth of those surveyed said they intended to leave the RPSGB next year.

Dr Karen Hassell told the RPSGB that a third of the Register was inactive

And if that wasn't enough of a problem, pharmacist David Morgan highlighted the poor working conditions faced by locums. His concerns over staffing levels, pay and workload were shared by other pharmacists in letters sent to the pharmacy press.

So, putting aside wider concerns over the impending changes to control of entry, the rollout of NHS LIFT schemes and the debate over fair funding of the new contract, it would appear that the biggest obstacle to community pharmacy's future could be that there will just not be enough pharmacists around in the future.

On a more general note, there were plenty of other headlines this year. The NHS Counter Fraud team continued to chase those generic drug manufacturers it believed were guilty of price fixing; pharmacy bloggers (online diarists) made an appearance on the worldwide web; Europe expressed a desire to see a free movement of health services; and the undercover *Which?* investigation saw the profession united in response.

Back at Lambeth, the registration and regulation of pharmacy staff and pharmacy technicians; the rollout of SOPs and CPD; the whopping rise in retention fees; the devolution review; and the debate over whether pharmacists should re-check bagged prescriptions all caused a stir among the profession, as did the over-arching health regulator CRHP when it began to flex its legal muscles.

Also this year, the first pharmacist supplementary prescribers made it onto the Register, Labour announced its *NHS Improvement Plan*, and the contents of Damien Hirst's Pharmacy restaurant were finally auctioned off.

Always in the news, the pharma industry also faced some difficult issues this year, from a new PPRS scheme, a health select committee investigation, the discovery of counterfeit Cialis and Reductil, to the Vioxx withdrawal. More positively, there has been the rollout of the world's first OTC statin and the promise of chloramphenicol eye drops as part of the community pharmacy armoury.

All in all, it has been a pretty eventful year, and this looks likely to continue. Among the prospects on the horizon for pharmacists are the PAGB supported self-care project in Erewash PCT, a pharmaceutical public health strategy, the Government's implementation of the recommendations from the Shipman Inquiry and not forgetting the very real possibility of independent prescribing.

Who said pharmacy was boring?

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PAGB

In its 85th anniversary year PAGB completes its short series of articles reviewing key topical issues around self-care. Here it comments on the importance of pharmacy staff training in the context of recent health policy developments affecting the future role of pharmacy

Brave **new** world

To make the most of the opportunities presented by the new contract, pharmacists must look much harder at skills training for all their staff, says **Mike Owen**, PAGB's communications and commercial affairs director

A 'new world' of possibilities is in the offing for pharmacy. The new pharmacy contract and the recent White Paper on public health are major milestones in the development of pharmacy, and a lot of eyes are on pharmacists to see if they are going to seize the undoubted opportunities.

That 'new world' includes continued expansion of the role of self-care in UK health policy and in the expected work of health professionals, including pharmacists.

New pharmacy contract

The new pharmacy contract, as it seeks to move pharmacy away from its traditional focus on dispensing and develop its wider clinical role, says little directly about self-care but the theme clearly helps to underline the greater emphasis indicated on public health promotion. Public health promotion by pharmacists will undoubtedly encourage greater consumer interest in self-care. Responsible self-care is a partnership between the individual and supporting health professionals.

Three particular service areas relating to self-care are incorporated under the new contract as 'essential' services:

Public health promotion – this will involve pharmacists and their staff giving opportunistic advice and counselling on major health topics (eg smoking cessation, CHD, high blood pressure and diabetes) to people who visit a pharmacy and, secondly, participating in six national or local public health campaigns a year on behalf of the local PCT.

Support for self-care – this will involve much that pharmacists do already – providing advice to people requesting help with the treatment of minor illness and long-term conditions and advising on the appropriate use of the wide range of non-prescription medicines. Pharmacies will also receive self-care referrals from NHS Direct and other healthcare professionals.

Signposting – this will involve pharmacy staff, when appropriate, advising people of other local health and social care providers and support organisations and directing them to the most suitable source of help.

The 'enhanced' services category of the new contract also suggests a number of services with a strong link to OTC medicines or self-care, which pharmacists might choose to develop in response to local needs and opportunities identified and agreed with the PCT. Examples include minor ailments schemes, smoking cessation services, CHD and diabetes screening, head lice management and compliance support.

White Paper on public health

Self-care was a more central influence behind the Government's latest White Paper, linked to the key aim of doing more to empower consumers and patients with more information, better support and more personalised healthcare choices. PAGB believes the paper represents a true cultural shift in public health policy away from a 'national sickness service' to more of a focus on health improvement and prevention.

Over the last 50 years, people's skills to look

after themselves have been eroded. People have become dependent on the NHS and, in particular, on the doctor to 'cure' all their problems. This White Paper is a positive step forward in providing a strategic platform to help give back to consumers and patients the confidence and support to make decisions about their health.

Informed patient choice and addressing health inequalities were key themes in the Paper, but so was the idea of cross-stakeholder partnerships and multi-functional working. These partnerships include not only the patient/consumer and health professionals but also a wide variety of other players, including local government, the NHS, business, retailers, the media and voluntary organisations.

Pharmacists will need to build and deepen their relationships, in particular with their local PCT, local GPs and other primary care professionals. Unless a 'partnership culture' does develop across primary care, there will be no real change in UK public health.

The White Paper actually did not contain much detail about the specific implications for pharmacists: we will have to wait for the launch of the Department of Health's pharmaceutical public health strategy early in 2005. But there was distinct recognition of the obvious fact that pharmacists work in the heart of the communities they serve and so can play a key role in helping the Government address major public health priority areas like smoking, sexual health, obesity, alcohol and mental health.

From retailer to health professional

Both the new pharmacy contract and White Paper are clearly seeking to enhance pharmacists' role as primary health professionals and, with the new payment approach set out in the contract, to foster much more of a focus on providing advice and service to consumers – similar to the new GMS contract for GPs.

But the evolution from dispenser/retailer to healthcare adviser/clinician is not going to be easy or rapid. Not least because pharmacies are crucially going to need new systems, better facilities, and closer integration with the rest of the local healthcare system (for example, integrated patient records) as well as new skills, knowledge and processes for pharmacy staff. All this is going to take years.

Pharmacists will also have to cope with many changes in the pharmaceutical and wider health environment – more POM to P switches, the growth of new pharmaceutical 'supply routes' (eg patient group directions, minor ailment schemes and supplementary prescribing), and freer pharmacy market entry regulations, to mention just a few.

In this changing environment pharmacists should see OTC medicines and food supplements as a vital contributor to their future, wider remit. Not only do OTC medicines form the backbone of the traditional everyday healthcare supply role of pharmacy and give a margin-based source of income, they help to attract a wider footfall into a pharmacy store, they help achieve a brighter and more interesting store, and they enable pharmacy staff to offer supplementary products to patients visiting for a prescription.

Crucially, in addition, OTC medicines provide a major platform for pharmacists to fulfil the wider public health, and not just self-care, support role desired by the Government. Future POM to P switches are moving towards treating more complex, long-term conditions – for example, heart disease and obesity – and so will be a key part of broader treatment and care decisions taken by pharmacists and other primary care professionals, who will necessarily have to work more closely together to ensure integrated care of patients.

To deal with this 'new world' pharmacists need to get serious about OTC medicines and wider skills training for their staff, as consumers and patients come to use their local pharmacy more. Hopefully, the new clinical governance requirements of the new pharmacy contract, including evidence of pharmacist CPD and use of patient satisfaction questionnaires, will be a major spur to enhanced training for all pharmacy staff.

Pharmacists will need to build and deepen their relationships, in particular with their local PCT, local GPs and other primary care professionals

During 2004, PAGB organised or attended several meetings between OTC manufacturers and pharmacists where there was debate about the current state of OTC knowledge and related skills among pharmacists and pharmacy support staff. Some of the key points of agreement which came out of these discussions were:

- Pharmacists' undergraduate/professional training includes little about OTC brands, the OTC marketplace; characteristics/attitudes/behaviour of OTC consumers; and how to sell medicines to consumers. This can lead to some pharmacists being reactive towards customers and conservative in making the most of potential OTC business.
- Pharmacy counter assistants receive a good core, introductory level of knowledge about OTC medicines when they initially start in their role – because there is a mandatory requirement – but there is no general, systematic approach for keeping assistants' knowledge up-to-date on an ongoing basis. The situation was seen as a problem particularly for staff working in small, independent pharmacies.
- Pharmacy counter staff generally receive little training in practical commercial and communication skills – for example, merchandising, listening and selling skills – to complement their product training. These staff also receive little insight into the attitudes and behaviour of OTC consumers. Since such staff are usually the very people who do most of the interacting with the consumer/patient, this was seen as a major weakness.
- OTC manufacturers are relied on to a large extent to provide product training for pharmacy staff. Training materials are valued if they cover topics in a truly objective way, in the context of the relevant category, and without too much overt branding.
- The pharmacist/pharmacy manager plays a crucial motivational and mentoring role for counter staff in terms of developing their knowledge and skills. Not all pharmacists are good at this aspect of their job.
- Counter staff value training highly as an important part of their job.

Some OTC manufacturers and pharmacy chains have produced excellent OTC related training for years, but it is pleasing that over the last 12 months or so the sector has started to see an increase in the range and depth of OTC training – including skills-based training – available to pharmacists and pharmacy support staff. The requirement for a training and information plan to be included now in a POM to P switch application will certainly help further to stimulate the sector's attention to training.

To help encourage high standards for OTC product training, PAGB, as part of a joint group of OTC manufacturers and retailers, developed earlier in 2004 a set of *Good Practice Guidelines for Developing OTC Product Training Materials*. In the form of a short A4 leaflet and available on PAGB's corporate website (*www.pagb.co.uk*), the document presents a summary checklist of 10 guiding principles to help design effective training programmes.

In 2005 PAGB will continue to support the development of OTC training further. Initiatives will include looking at pharmacy undergraduate education with professional and educational institutions; sharing PAGB's substantial research and knowledge base about OTC consumers; contributing OTC-related training to new pharmacy managers' training programmes; and launching a web-based directory of OTC training and educational facilities offered by OTC manufacturers. PAGB will also be widening the appeal of its well-established OTC product directory.

In the end, it's down to the pharmacist though. The pharmacist is the most crucial factor in seeking to enhance the knowledge and skills of pharmacy staff. Unless pharmacists and pharmacy managers themselves take a proactive and enthusiastic stance towards staff training and development generally – not just about OTC medicines – pharmacy will not be able to respond fully to the new opportunities including self-care and public health, facing the profession.

Next year will see the start of implementation of the new pharmacy contract. Go on, pharmacists, show what you can do!

The final draft of the human genome was announced in October, so what happens now? Marianne MacDonald asks Dr Justin Lamb just how functional genomics will revolutionise clinical therapy

Gene genie

"Our objective is to provide a comprehensive catalogue of the function of all of the genes in the genome, and all of the bioactive small molecules known to man," explains Dr Justin Lamb, of his work as a senior scientist at the Broad Institute in Cambridge, Massachusetts, where the human genome was first sequenced.

Put more simply and, in recognition of his roots as a UK pharmacy graduate, Dr Lamb elaborates further: "It's sort of like Martindale, written in the lexicon of the genome." The multi-million dollar project Dr Lamb heads has been dubbed as the next phase of the human genome project. As far as he's aware, he's the only person at Broad – formerly the Whitehead/MIT Center for Genome Research – with a degree in pharmacy.

While studying as one of the very last graduates of Heriot-Watt's pharmacy course – which ceased in 1989 – seems a long way from the US scientific elite, it was a clear path for Justin. "I was attracted to pharmacy as a degree because I thought it would be like applied organic chemistry. It wasn't really, but the undergraduate course contained just enough of everything to give me a grounding in all of the disciplines of modern biomedical and pharmaceutical research."

This was confirmed during his pre-registration industry placement at Pfizer. "The world was big and pharmaceutical discovery was cool!" So Dr Lamb undertook a PhD in cellular/molecular biology and pathology back home at the Aberdeen University School of Medicine.

His thesis work on the molecular responses of cells to drugs and nutrients attracted the attention of a Harvard professor, who asked Dr Lamb to undertake research in his lab at Boston's Dana-Farber Cancer Institute (a leading cancer centre affiliated to Harvard Medical School). Further postdoc work on the mechanism of action of a key human oncogene – cyclin D1 – not only helped elucidate its workings but also revealed a hitherto unrecognised interdependence with other genes in cancer development.

In 'gene'ius

So how did this lead to Dr Lamb's current project? "The new functional genomics technologies that arose through work on the first draft of the human genome sequence coincided with a time when I had more or less exhausted conventional approaches to the cyclin D1 mechanism."

The Broad Institute was looking for important problems that could be addressed by these new technologies. Dr Lamb elaborates: "Identifying the genes that cause disease is good for diagnosis and prognosis, but if you want to find therapeutics you need to know how they cause disease. That's why uncovering the mechanisms of gene action is the key challenge."

His work at the Institute has seen Dr Lamb's group meet this challenge in a novel way, becoming probably the first in the world to use high-density gene expression profiling technology called GeneChips to discover the mechanism of action of a human oncogene at the molecular level. "It's a unique way to look at biological states. Essentially they're microchips upon which every gene in the human genome is arrayed, allowing you to measure the level of each one simultaneously in response to a perturbation of interest."

These GeneChips are now being used to measure the activity of all possible chemical and genetic perturbations. It's a massive project. "We estimate that the total volume of raw data will greatly exceed that of the entire human genome sequencing project," says Dr Lamb.

Once the data is captured it will form the foundation of an encyclopaedia of gene and drug actions. "With genome-wide profiles of human diseases we can, hopefully, simply read off the genes that underlie, and the drugs that reverse, those diseases from our computer screen."

The pilot project is now complete and Dr Lamb believes it's an approach to drug discovery that's going to work. Clearly, he's not alone. "We've had lots of interest from big pharma companies!"

Hardly surprising, given the enormous potential of his work. But how soon can we see the benefits? "It's hard to say. If we compare with the genome sequencing, which was expected to take decades to complete, it took much less time because technology development is so dynamic in this domain."

Dr Lamb believes the same will happen with his group's work. "If it turns out to be as useful as we think then improved technology will prompt a quick completion. If it isn't that useful, we'll learn the lesson and try a different approach." Dr Lamb concludes: "It's an unsatisfying answer for those who want a timeline, but we know there's extraordinary discovery potential in genomic approaches; it's just finding a systematic way to uncover it."

Dr Justin Lamb and the 'GeneChip' used in his research into the action of a human oncogene at the molecular level

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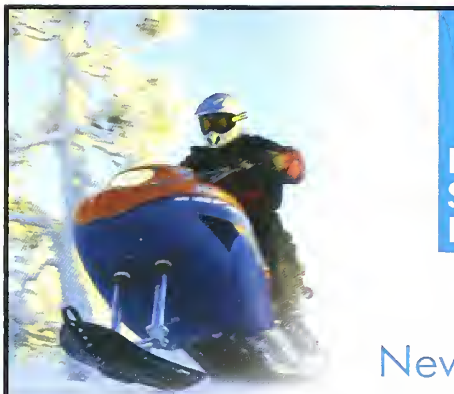

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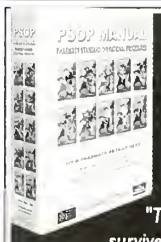
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All I want for Christmas is **peace, happiness**... and a **flying scooter**

Most people will be eagerly anticipating a few days off to recover from the pre-Christmas pandemonium (why do some patients need an extra month's medication because their GP surgery and pharmacy is closed for a day or two?), in addition to the contents of their Christmas stocking as reward for all their hard work during the year.

But though many will be happy with the usual tangerines, chocolates and favourite bottles of alcohol, *C&D* wondered what some of the leading lights of the profession had put on their Christmas wish list. So we asked and got an interesting mix of responses.

First up, Royal Pharmaceutical Society president **Nicholas Wood** who said: "It's been an interesting year to say the least for the Society and the profession as a whole. But with both the new pharmacy contract and the Society's new Charter arriving in quick succession many may rightly feel that Christmas has come early. I wish *C&D* readers all the very best for the holiday season." Thanks very much Mr W.

Company Chemists' Association chief executive **Colin Baldwin** also admitted to being preoccupied with the contract, saying he hoped it would be successfully implemented: "Father Christmas will hopefully leave us all with a present of the latest, much sought after bestseller with the snappy title *How to integrate within primary care in a profitable and sustainable manner*."

Anyone wishing to buy a copy before December 25 may be sad to hear that Santa's helpers are still busy writing (according to Mr Baldwin), but be sure to keep an eye on your local bookstore for signings.

Another person mentioning the contract is **Frank Owens**, Scottish Pharmaceutical General Council chairman, though he claimed to be suffering from "an acute case of new contractitis" and was looking forward to spending Christmas recuperating. He's optimistic Father Christmas will deliver some funding, and said hopefully: "As the Scottish contract is not due out until April 2006, maybe Santa will be good enough to drop two caches – one this Christmas, one the next."

He added: "I'll welcome cash gifts from any political benefactors such as the tooth fairy. Other useful gifts might include the goose that laid the golden egg and the spinning wheel that spun the golden thread." Oh dear. How will Santa get those down the chimney without waking anyone in the Owens' household?

Numark chief executive **David Wood** didn't mention the contract, but was no less political in his request for "an OFT that understands community pharmacy". Maybe Santa will pass his appeal on. It's up to Boots superintendent **Pradip Patel** to ease the tone with his wish for "peace, happiness and great health" for all his pharmacist colleagues.

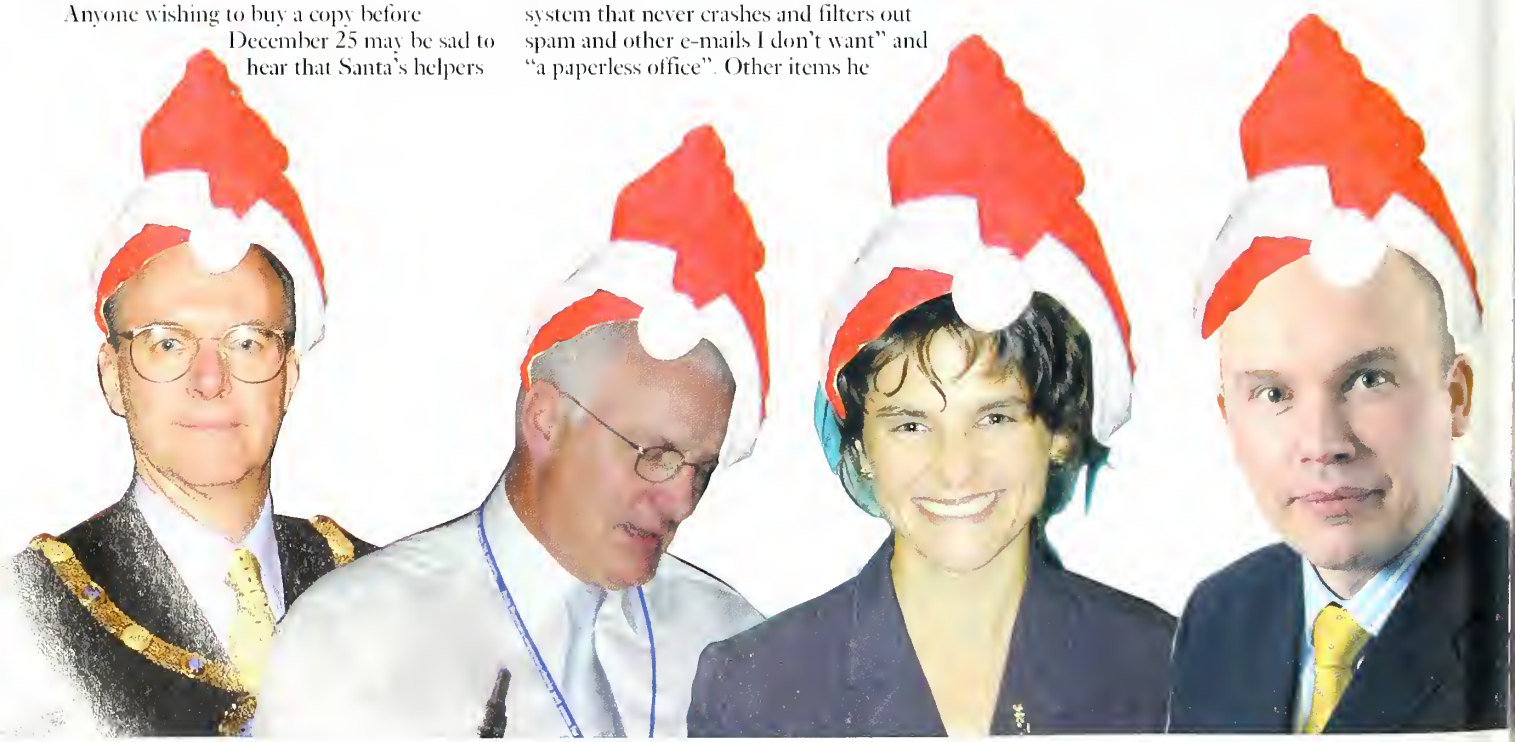
The National Pharmaceutical Association's office in St Albans must be a very chaotic place if **John D'Arcy's** list is anything to go by. The NPA chief executive said he wanted "an e-mail system that never crashes and filters out spam and other e-mails I don't want" and "a paperless office". Other items he hopes to find in his stocking include an accurate train timetable, 25 hours in every day, and a properly paid for community pharmacy service. Santa's elves may find their giftwrapping skills tested more than usual.

On a more irreverent note, Pharmacists' Defence Association general manager **John Murphy** asked: "A letter from Wayne Rooney asking if we will take him back, because he wants to be guaranteed European football next year." But maybe he isn't such a stalwart Everton fan after all, as he added: "Please note I am writing this early in December."

PharmacyHealthLink chief executive **Miriam Armstrong** seems to be feeling the current cold snap more than most, asking for "a two week 'liveaboard' diving holiday in the Galapagos Islands, a Snugg winter wetsuit for UK surf, and Selfridges gift vouchers so I can buy a fake fur coat and accessories in the sale".

Finally **Chris Street**, Moss Pharmacy health and pharmacy adviser, tried to be sensible, saying he'll need "one of those nifty handheld computers" to help him cope with the new contract next year. But what he'd really like is a flying scooter to help him avoid the daily commute, though he added "I'm not sure if it's available yet".

Probably not. They don't seem to be advertised on the eBay website where it seems possible to buy anything, but if anyone can sort it out it's good old St Nick. Looks like he's going to have a busy festive season.



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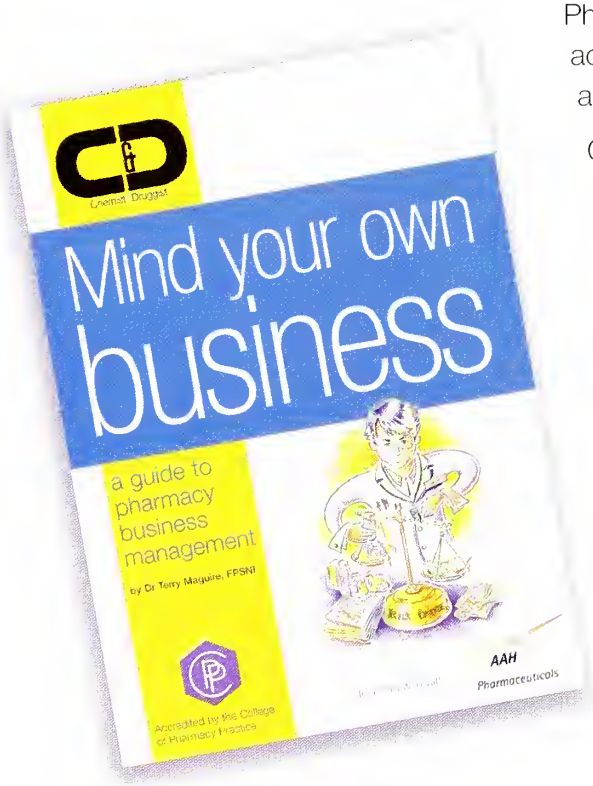

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